

**Assessment of Postural Control, Dizziness and Musculoskeletal Impairments
in Post-Concussion Children and Adolescents**

by

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BROAD ABSTRACT

This three-paper, five-chapter dissertation aimed to examine the three commonly seen impairment categories post-concussion i.e. postural control, musculoskeletal impairments and dizziness to provide clinicians with clinically useful information regarding these impairment categories. This dissertation also provides the details on psychometric properties of a recently developed patient reported measure to evaluate perceived disability due to post-concussion dizziness in children and adolescents.

There were three independent studies that were associated with this dissertation. The first study provides details on the relative and absolute reliability postural control measures in typically developing children and adolescents. The second study describes the various impairment categories that were observed in children and adolescents post-concussion. This study will aid towards formulation of a population specific structured tool for the cervical spine impairments following concussion. The final study evaluated the psychometric properties of the Dizziness Handicap Inventory- children and adolescents (DHI-CA) in post-concussion children and adolescents. This study will aid clinicians in making informed clinical decisions while evaluating perceived disability due to dizziness following a concussion in children and adolescents.

Chapter I of this dissertation provides background information for each of the three studies and chapter V describes the integrated discussion and a broad conclusion.

CHAPTER I

Background

Concussion: definition and prevalence

Several definitions of concussion have been proposed over the years. Milder forms of traumatic brain injury (TBI) have been previously described in literature by different overlapping terms such as concussion, mild TBI or mild closed head injury.¹

One of the earliest definitions of concussion dates back to 1966 where the committee on head injury nomenclature of neurologic surgeons defined it as “a clinical syndrome characterized by the immediate and transient posttraumatic impairment of neural function such as alteration of consciousness, disturbance of vision or equilibrium, etc., due to brain stem dysfunction”.² This definition was widely recognized and used until 1997, when the American Academy of Neurology proposed another definition as “any trauma induced alteration in mental status that may or may not include loss of consciousness”.³

The centers for disease control and prevention (CDC) defined concussion as “a type of TBI caused by a bump, blow or jolt to the head or by a hit to the body that causes the head and brain to move rapidly back and forth.”⁴ Most recently, in the 2017 Concussion in Sport Group consensus statement, concussion was defined as “a TBI induced by biomechanical forces that may be caused either by a direct blow to the head, face, neck or elsewhere in body with an impulsive force transmitted by the head.”⁵

Concussion can occur via several mechanisms including a direct blow to head, neck, face or elsewhere on the body associated with impulsive forces transmitted to the head.^{1,5}

Concussion has been reported to produce “graded set of clinical symptoms that may or may not involve loss of consciousness” with sequential resolution.⁵ The symptoms produced by concussion are rapid onset, short lived and present mostly as functional disturbances rather than structural injury.¹

Of all the TBIs, concussions are the most common with up to 3.8 million recreation or sport related concussions occurring annually in the United States.¹ It is noteworthy that, this number may actually be lower than the actual incidence since many concussions go unrecognized.^{6,7}

Concussion in the youth

TBI is one of the major causes of mortality and morbidity in children and adolescents.^{8,9} Concussion in children and adolescents can occur from various mechanisms and activities that vary by age.¹⁰ In younger population, i.e. 15 years or below, incidence of TBI is 180 per 100,000 children per year out of which 85% are classified as mild injuries.¹¹ It has been estimated that over 1 million children sustain TBI annually and TBI is responsible for more than 250,000 pediatric hospital admissions.¹²

It has been reported that rate of concussion is higher in high school athletes than that of older athletes.¹³ According to the CDC, from 2001 to 2009, there has been a 62% increase in number of ED visits by persons 19 years or younger following a sport related concussion.¹⁴ An increase of up to half a million emergency department visits for concussions was reported in children aged 0-14 years in the last decade.¹⁵ In any given year, 43200 to 67200 of the 1.2

million total high school football players sustain concussions with adolescents 15-19 years being most susceptible.¹⁵⁻¹⁷

Children and adolescents may be at a higher risk for concussion with longer recovery periods and increased severity as compared to adults.^{13,18} Bey and Ostick reported that sports and bicycle accidents were the most prominent causes of sustaining concussion in 5-14 year age group.¹⁹ It has been suggested that younger athletes demonstrate considerable differences from adult athletes in terms of biomechanical properties of injury, variations in pathophysiological responses to injury, neurobehavioral outcomes and contextual expectations.²⁰ Additionally, factors such as weight gain during adolescent growth spurt may increase the force and momentum during collision.²¹

Collins and colleagues reported that high school athletes may take longer to recover as compared to collegiate athletes based on neuropsychologic test results.²² Following concussion, there is a drastic increase in the amount of Glutamate and other excitatory neurotransmitters such as N-methyl-D-Aspartate (NMDA) and 2-amino-3-propanoic acid (AMPA) receptors that results in massive influx of Sodium and Calcium ions. This in turn leads to upregulation of sodium-potassium pump to restore normal resting membrane potential.²³

Disturbances in cerebral blood flow in terms of autoregulation and vascular reactivity impairments have been observed following concussion.²³ It has been proposed that children and adolescents may experience more prolonged and diffused cerebral edema and an acute increase in cerebral blood flow (CBF) following a concussion as compared to adults, suggesting that age may play a role in modulation of the CBF.^{23,24} This alteration in the CBF in turn can lead to an increased risk for secondary intracranial hypertension and ischemia.²⁵ A combination of these

factors may lead to longer recovery periods and could increase the likelihood of severe or permanent neurological deficits.^{22,25}

It has been suggested that teenage and high school age might be the most vulnerable to demonstrate slow recovery.²⁶ Iverson and colleagues reported that following a concussion, professional athletes recovered faster as compared to college athletes and high school athletes, who demonstrated most delay in recovery.²⁷ Additionally, it was reported that children with prior history of mental health problems or migraines may be at a greater risk for prolonged recovery.^{13,20,27} Pre-existing co-morbidities including learning disabilities and Attention Deficit Hyperactivity Disorder (ADHD) have been identified as risk factors that contribute to prolonged recovery following concussion in children and adolescents.^{13,20} It is also noteworthy that younger children may have less ability to conceptualize and verbalize their symptoms as compared to teenage and high school population.²⁶

It has been a common misinterpretation that injury from concussion is considered less severe than mild TBI, which may result in premature return to school or activity.²⁸ On the contrary, concussion in children and adolescents may lead to acute and long-term physical, behavioral and neurocognitive effects that may impact learning and school performance.^{13,29-31} Additionally, managing a child or adolescent with concussion requires active involvement of the parent as the parent is an important participant in the process of recovery, return to school, sports and everyday home and social activity.²⁰ Taking the above factors into consideration, systematic tracking of young athletes through conducting a comprehensive physical examination and administering standardized symptom inventories has been recommended.²⁰

Previous concussion guidelines did not include age and developmental considerations while determining return to play criteria.³² In a recent study, Davis and colleagues indicated that

management of sport-related concussion in children must be different from adults.³³ Also, it was recommended that post-concussion management for children may need to be more specific according to the age groups and they proposed three age groups i.e. 5-8 years, 9-21 years and 12 years.³³

Clinical presentation and assessment

A range of clinical symptoms, physical signs and neurobehavioral features characterize concussions. The clinical presentation of concussion may include somatic features such as headache, neck pain, nausea, vomiting, dizziness, visual problems, sensitivity to light and noise; physical signs such as postural control and gait impairments and fatigue, cognitive features such as feeling like in a fog, difficulty concentrating, difficulty remembering and feeling slowed down; emotional symptoms including irritability, sadness, nervousness and sleep/wake disturbances including insomnia, difficulty falling asleep, and drowsiness.⁵

Diagnosis of concussion involves numerous areas of assessments including clinical symptoms, physical signs, cognitive and sleep impairments and neurobehavioral deficits.⁵ The sports concussion assessment tool-5 (SCAT-5) which incorporates the Maddocks' questions and standardized assessment of concussion (SAC) represents a comprehensive and the most well-established instrument available for sideline assessment.⁵

The Berlin guidelines recommend a comprehensive assessment following a concussion. The assessment must include a comprehensive history, neurological examination that consists of mental status, cognitive functioning, ocular & vestibular function, gait, postural control and sleep/ wake disturbances.^{5,34} Evaluation of different phenotypes of concussion is now considered an important part of clinical assessment.³⁴ Key components of concussion phenotypes include cognitive function, ocular manifestations, affective function, cervical spine function,

cardiovascular system and vestibular system.^{5,34} A significant overlap has been documented between the clinical phenotypes and it has been recommended that the healthcare providers must consider each potential phenotype in patients with delayed recovery.³⁴ The signs and symptoms following concussions can range anywhere from several minutes to months or even longer.^{35,36}

Postural control and concussion

Definition

Postural control has been identified to be associated with maintenance of specified postures, voluntary movements and reaction to an external disturbance such as perturbation.³⁷⁻³⁹ Together, posture and equilibrium components are responsible for maintaining stability of the body during various functional activities.^{40,41} Nashner suggested that a global scheme for combining information from various sensory systems throughout the body is essential for interpreting orientation and motion information during movement.⁴² Upright bipedal stance depends on vision, vestibular and somatosensory inputs to provide postural control and appropriate alignment of body segments with respect to gravity.^{39,42}

Postural control impairments in children post-concussion

Post-concussion postural instability has been reported in multiple studies.^{9,43,44} Numerous structures ranging from peripheral sensory receptors to central structures including the cerebellum, cerebral cortex and brain stem have been involved in the perception and integration of sensory information.⁴⁴ Sensory interaction impairments, including interactions between visual, somatosensory and vestibular systems, has been identified as one of the primary contributing factors towards postural instability.⁴⁴ Previous research has reported that postural impairments may most likely occur secondary to the inability to resolve sensory conflict that comes from unstable surfaces or from inaccurate inputs by visual cues.^{44,45}

Examination of postural control in children may reveal subtle motor deficits.⁴⁶ Persistence of these deficits in later childhood and adolescence can indicate motor dysfunction and may be associated with atypical neurological function.^{46,47} These post-concussion postural

control impairments limit children's ability to participate in school related activities and return to sports.^{16,48} Regaining clinically normal postural control has been identified as one of the indicators of post-concussion symptom resolution.⁵ Examining postural stability, therefore, has been identified as an indirect means of identifying neurophysiological abnormalities post-concussion and serves as an essential tool to determine recovery.^{43,44}

Assessment of postural control

A comprehensive assessment of postural control is essential in clinical practice both for diagnostic and therapeutic reasons.⁴⁹⁻⁵² Both instrumented and clinical measures are available for assessment of postural control.

Instrumented measures assess the amplitude of center of pressure (COP) while maintaining the center of gravity (COG) within the base of support (BOS).⁵³ Larger amplitude COP indicates greater motion of the COG and greater muscle activity requirements to maintain postural control.⁵³ These measures include posturography using various force platforms.

Clinical measures include both static and dynamic assessment of postural control. Since performance of a task is influenced by task, environmental and individual constraints, postural control requires continual adjustment to carry out a successful motor task.⁵⁴ Hence, clinical measures evaluate postural control in terms of task performance.⁵⁴ Numerous clinical measures are available currently including timed up and go, functional reach test, balance error scoring system, balance evaluation systems test etc. as well as batteries of tests including movement assessment battery and Bruninks Oseretsky test of motor proficiency 2.

While instrumented measures focus on sensory organization tests and limits of stability, clinical tests focus on motor and cognitive systems (dynamic postural control and dual tasking) along with sensory organization.^{55,56}

Clinical utility of a postural control measure depends on its ability to reproduce reliable and error free scores.⁵⁷ However, research on measurement properties of postural control measures in children and adolescents remain sparse at this time.

Cervical Spine function and concussion

Cervical musculature is responsible for managing 80% of mechanical load and providing stability to the cervical spine.⁵⁸ Upper cervical spine provides afferent input for head and neck position to the central nervous system (CNS) and has neurophysiologic interaction with the sensory and motor nuclei of the brain stem. Additionally, somatosensory information from the cervical spine in combination with visual and vestibular inputs contributes towards postural and oculomotor regulation.^{59,60}

Injury to the cervical spine may result from acceleration-deceleration and rotational forces that are sustained in concussion.^{61,62} Axial loading, hyperflexion and hyperextension of cervical spine are the most frequently reported mechanisms of injury to the cervical spine associated with various sports such as football, hockey and wrestling.^{9,63} Cervical spine injuries including muscle strain, facet joint injuries and nerve root injuries may result from the neck being forced to excessive range of motion during collisions.^{64,65}

A variety of signs and symptoms are observed post-concussion, some of which can be associated with injury to the cervical spine.^{5,66} Cervical spine injury can be structural or functional and is associated with symptoms such as dizziness, headache, neck pain and blurred vision.⁶⁷⁻⁷⁰ Zygapophyseal joints have been identified as the most common source of neck pain post-injury.⁷¹ Also, factors such as tension in cervical muscles, bad posture and physical activity performed with faulty motor strategy contribute towards neck pain and restricting movement.⁷¹ These symptoms can negatively impact the life of an individual in regards to participation in sports, activities of daily living, socializing and overall quality of life (QOL).⁷²

Children and adolescents may be at higher risk for concussion as they have greater head mass to body ratio and weaker neck musculature as compared to adults.⁷³ Compared to adults,

the reduced development of neck and shoulder muscles in children and adolescents can potentially contribute to the ineffective energy dissipation from the head impact to the rest of the body.¹³ Also, immaturity of the developing CNS, larger head to body ratio, thinner cranial bones, larger arachnoid space and difference in the cerebral blood volume have been reported as risk factors in terms of differences in vulnerability to concussion and recovery post-concussion between the pediatric and adult population.¹³

Poor neck strength is a potentially modifiable risk factor that contributes to higher concussion risk in athletes.⁷⁴ Weak neck musculature may lead the athletes to experience greater linear and angular head displacements, velocities and acceleration after impact.⁷⁵ It has also been reported that an athlete with stronger neck muscles and normal neck mobility can generate greater absolute tensile forces and produce greater neck stiffness as compared to an athlete with weaker neck muscles or limited ROM.⁷⁶ Higher neck strength and greater tensile force have been reported as a protective mechanism as they may potentially reduce risk of sustaining concussion.⁷⁵ Additionally, as compared to young adults, adolescents have been found to have decreased active cervical spine rotation. This decreased cervical spine range of motion limits the ability of the athlete, during an impact, to move out of the way of the path of the torso, thereby increasing the risk of injury.⁷⁷ A detailed evaluation of the cervical spine, therefore may contribute towards identifying targeted interventions for these athletes post-concussion.

Dizziness and concussion

Dizziness has been defined as “a constellation of symptoms including vertigo and lightheadedness with motion as a result of concomitant vestibular injury following concussion.”⁷⁸ Vertigo is defined as the “hallucination of movement” whereas lightheadedness is caused by diminished cerebral perfusion or brief autonomic dysfunction.⁷⁹ However, recent evidence suggests that post-concussion, both vestibular and cervical spine involvement may contribute towards lasting dizziness.^{69,80} Post-concussion dizziness can be explained by a central functional disturbance, peripheral vestibular dysfunction or impairments in cervical proprioception.⁸¹ Causes for peripheral vestibular dysfunction can be attributed to unilateral vestibular weakness, benign paroxysmal positional vertigo, perilymphatic fistula, otolithic injury or superior canal dehiscence.⁷⁸ Also, cervical spine mechanoreceptor dysfunction along with dysfunction in cervico-collic reflex, vestibulo-collic reflex and vestibulo-ocular reflex has been reported to contribute towards cervicogenic dizziness.^{82,83} Anatomic proximity of the vestibular nuclei to cervical vertebrae may explain the mismatch in sensory information that may cause an interplay in symptoms.^{81,82,84} Injury to cervical spine can affect numerous structures including cervical nerve roots, cervico-thoracic and cervico-scapular musculature and cervical intervertebral discs along with zygapophyseal joints. An injury to these structures can contribute towards post-concussion dizziness, postural control impairments and neck pain.^{34,85,86}

Up to 80% of all cases with concussion report dizziness during the first few days post-injury.^{14,87} Following concussion, the natural course of recovery from dizziness is longer as compared to the non-dizziness oriented symptoms and may last for several years after the event.^{36,81} It was reported by Lau and colleagues that athletes who reported on-field dizziness

were more likely to have post-concussion symptoms after 21 days as compared to athletes who denied dizziness (Odds ratio = 6.3).⁸⁸

Dizziness following concussion could be related to symptoms such as lightheadedness, weakness, imbalance, faintness or perception of moving or vertigo.⁷⁹ Chamelian and colleagues reported that dizziness was an adverse prognostic indicator and was an independent predictor of return to work in adults with mild to moderate TBI.^{5,89} In children, this may manifest in the school affecting their school performance, communication abilities, and psychological frame of mind. Additionally, dizziness may result in nausea and vomiting, poor postural control, coordination impairments, difficulty with visuospatial orientation, falls during participation in play activities or sports. These impairments can significantly can negatively impact the life of an individual in regards to participation in sports, activities of daily living, academic performance, socializing and overall Quality of Life (QOL).⁷²

Assessment of dizziness

Several assessment methods are currently available for evaluating vestibular function in adults ranging from complex instrumented measures to simple self-reported subjective measures.

Objective measures: A variety of lab-based objective measures are currently available to test the both vestibular and postural control systems that may be involved with dizziness. These measures include video nystagmography (VNG) recording of eye movement, Vestibular Evoked Myogenic Potential (VEMP)caloric testing, rotary chair, platform posturographic testing and electronystagmography.^{90,91 92}Caloric testing and rotatory chair test primarily focus on evaluating vestibulo-ocular reflex function.^{92,93} Traditionally. electronystagmography has been considered the ‘gold standard’ for testing dizzy patients. However, the advent of video nystagmography has

offered several advantages over traditional protocols in terms of its ability to record eye movements using digital video image technology.⁹²

Subjective measures: Since dizziness is a highly subjective construct, subjective medical history and self-reported measures are widely used and are of great importance in determining the cause of dizziness as these provide valuable insight on exact descriptions and triggers of dizziness.^{92,94} Previous research has recommended that age appropriate, validated symptom rating scales should be utilized as a part of diagnostic evaluation in children who present with suspected concussion.³³

The Vertigo Symptom Scale (VSS) is a disease-specific subjective questionnaire used to quantify balance disorders, somatic anxiety, and autonomic severity symptoms and consists of two subscales.⁹⁵ The Vertigo scale (VSS-VER) subscale primarily assesses vestibular system and the Anxiety and Autonomic symptom subscale (VSS-AA) assesses symptoms associated with autonomic arousal or somatic system.⁹⁵

The Dizziness Handicap Inventory (DHI) was developed and validated by Jacobson and Newman as a self-reported questionnaire for dizziness. The DHI evaluates the impact of dizziness on quality of life under various domains including physical, functional and emotional domains. The DHI is one of the most widely accepted and commonly used tool for evaluation dizziness. The DHI has been adapted in several languages and for different age groups.⁹⁶⁻⁹⁹ Recently, DeSoussa and colleagues adapted the Brazilian Portuguese version of the adult DHI to the children and adolescent population which was named DHI- Children and Adolescent (DHI-CA).⁹¹

Limitations of previous work and rationale for the proposed studies

Physical therapists are instrumental members in multidisciplinary management of concussion as they contribute significantly to the process of evaluation and treatment post-concussion. Considerable differences exist between children and adolescents and adults' post-concussion.

Clinical practice guidelines contribute towards continuous enhancement of the quality and process of care. They are instrumental in assisting healthcare providers in making well informed decisions under specific clinical circumstances.¹⁰⁰ The clinical practice guidelines for peripheral vestibular hypofunction highlight the paucity of research on assessment and management of vestibular dysfunction in children.¹⁰¹ Also, since postural control is still developing in children, the rehabilitation strategies might differ with age and further research on assessment of postural control in this population has been recommended.¹⁰¹ It is also noteworthy that practice guidelines for management of cervical spine impairments are currently unavailable for individuals below 18 years of age. Recommendations have been made in the past that this population must be evaluated and managed differently from adults due to considerable anatomical and physiological differences.¹³ However, currently there is a gap in literature on the characterization of cervical spine impairments, as well as information regarding valid and reliable evaluation tools for children and adolescents post-concussion.

To maximize the applicability of clinical practice guidelines in improving the continuum of care over a wider age spectrum, it is important to fill the gaps in evidence that currently exist in this subset of children and adolescent population. By addressing the limitations above,

physical therapists will be able to evaluate population specific impairments and provide impairment-specific interventions.

Rationale for the first study

Although, there are several measures of postural control available to the clinician, the choice of the right outcome measure depends, in part, on how reliable the measure is in assessing postural control in the population subset. Children and adolescents post-concussion represent a unique group of individuals as these individuals are otherwise typically developing prior to concussion. The neuromotor impairments including balance deficits that are seen post-concussion may be reversible unlike other neuromuscular disorders such as cerebral palsy, muscular dystrophy etc.^{23,102} Post-concussion children and adolescents therefore may relate better to outcome measures that have been tested in the typically developing children. At this time, the literature regarding reliability assessment of postural control outcome measures for typically developing children and adolescents is scant.

Hence, the purpose of the first study was to describe the reliability, minimal detectable change and standard error of measurement of postural control measures along with reporting the methodological qualities of the studies that investigated these parameters in typically developing children and adolescents.

Rationale for the second study

The mechanism of injury in concussion and whiplash is almost identical, with a significant overlap in symptom expression.³⁴ Recent evidence suggests that post-concussion symptoms demonstrate overlapping in terms of cervical spine and vestibular system involvement. Also, documentation exists on the fact that children and adolescents demonstrate considerable differences in cervical spine anatomy and physiology as compared to adults. The evidence is still sparse in terms of identifying impairment patterns related to cervical spine that are specifically seen in this population.

Examination and treatment methods for concussion and cervical spine injury are different despite of almost identical symptoms.⁶⁰ Currently, the prevalence of cervical spine pathology in concussed patients is unknown.³⁴ There are no standardized physical therapy evaluation formats available for evaluating cervical spine post-concussion for children and adolescents. There exists very limited data on the patterns of clinical presentation, impairments and examination measures that are currently utilized for post-concussion children and adolescents, establishing the need for further description of these patterns in children and adolescents. Ability to accurately identify symptoms and impairments will not only provide the necessary information to develop standardized evaluation tools, but will also be a step towards allowing therapists to provide appropriate prescription for cervical physical therapy that can be instrumental in reducing symptoms intensity and speeding up the process of recovery.

The purpose of the second study therefore was to provide a description and characterization of the impairments relevant to the cervical spine observed post-concussion in children and adolescents.

Rationale for the third study

The impact of dizziness in individuals post- concussion on QoL and participation warrants finding ways to systematically assess dizziness. Among the currently available measures of dizziness, the DHI is widely recognized and used to assess dizziness. The DHI-CA was recently developed from the original DHI for the assessment of dizziness in children and adolescents.

The validity, responsiveness and internal consistency of the DHI-CA has not been examined in post-concussion children and adolescents. The purpose of the third study, therefore, was to evaluate the validity, responsiveness and internal consistency of DHI-CA in children and adolescents post-concussion. The results of this study would contribute towards meeting the need to have population and diagnosis specific measures to accurately evaluate dizziness.

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CHAPTER II

Measurement error in postural control measures in typically developing children: A systematic review

Abstract

Background. A comprehensive clinical assessment of postural control is essential for both diagnostic and therapeutic reasons in clinical practice. Use of non-reproducible postural control outcome measures may result in over or underestimation of performance.

Purpose. The purpose of this study was to, 1) report the test-retest, intra-rater and inter-rater reliability of postural control outcome measures, to 2) report the minimal detectable change and standard error of measurement (SEM) of these outcome measures and to 3) describe methodological and reporting qualities of the studies that examined the reliability of postural control outcome measures in typically developing children with a mean age of 8-18 years.

Methods. An electronic database search of PubMed and CINAHL was performed for literature published between 1985 until February, 2018 using search terms for reliability, children and balance. Quality of reporting was assessed with the Strengthening the reporting of observational studies in epidemiology (STROBE) checklist. Methodological quality was assessed using the modified Quality Appraisal tool for Reliability studies (QAREL). MDC and SEM were calculated from the information available in the studies.

Results. Of the 5820 studies screened, 25 were included in the final qualitative analysis. Twenty-two different postural control measures (8 static, 14 dynamic) were identified. Among static measures, the Clinical Test of Sensory Interaction in Balance (CTSIB) demonstrated highest test retest reliability for sway velocity across all 4 test conditions when used with the AccuGait force plate (ICC = 0.72-0.91, CI = 0.54-0.95). The instrumented Balance Error Scoring System (BESS), BESS and modified BESS demonstrated moderate to good test-retest reliability (ICC = 0.5-0.88 respectively). Among the dynamic measures, the modified functional reach (mFRT) and one leg hop tests demonstrated highest test-retest reliability (ICC = 0.95 (0.91-

0.99); 0.95 (0.91-0.97)). MDC values for TUG ranged from 0.6-0.9 seconds. MDC for limits of stability ranged from 0.1-0.3 seconds for reaction time, and 1.5-3.4 degrees/sec for movement velocity. MDC values for other measures were not comparable across studies.

Conclusion. The BESS demonstrates acceptable reliability across studies and may be used for evaluation of static postural control in typically developing children. The CTSIB may provide reliable data when used with the AccuGait. The mFRT, one leg hop, Balance Evaluation Systems Test (BEST and mini BEST) provide promising findings. Single study observations and methodological inconsistencies warrant cautious interpretation of findings.

Clinical Relevance. This review discusses the assessment of absolute and relative reliabilities, and MDC values in the typically developing children for static and dynamic postural control measures as well as the assessment of methodological quality and clarity of reporting in the included studies. By providing a comprehensive description of the reliability, MDC and study quality, this review will aid the clinician in making informed decisions when selecting an outcome measure.

Keywords: reliability, balance, typically developing

Introduction

Postural control or postural stability is the foundation for all voluntary motor skills essential for everyday function and is a prerequisite for normal motor development in children.^{1,2} Static postural control or stability has been defined by Nashner as the ability to limit the movement of center of gravity (COG) when the base of support remained fixed.³ Static postural control differs from dynamic postural control in that it pertains to the ability to shift and control the COG within a fixed base of support, whereas dynamic postural control describes the ability to move and control the COG within a changing base of support.³

A comprehensive clinical assessment of postural control is essential for both diagnostic and therapeutic reasons in clinical practice. Sequential administration of postural control tests is instrumental in measuring change attributed to progression of disease, recovery or rehabilitation.⁴⁻⁷

Clinical utility of a postural control measure depends, in part, on its ability to reproduce reliable and error free scores. Reliability of outcome measures is also required to track efficacy of treatments and to monitor progression following an intervention.^{8,9} Use of non-reproducible postural control outcome measures may lead the clinicians to over or under estimate the performance.¹⁰ Therefore, accurate quantification of measurement error in postural control outcome measures in typically developing children is warranted.

Postural control in typically developing children is quantified using a myriad of outcome measures ranging from relatively simple clinical measures to more complex and instrumented measures.¹¹ Although previous reviews have assessed the reliability of postural control outcomes in different neuromuscular conditions,¹²⁻¹⁴ evidence for reliability of postural control outcomes in typically developing children remains sparse. There is a critical need to evaluate the reliability of

postural control outcome measures in typically developing children before they can be utilized in heterogeneous clinical populations with varying degree of severity.

Even though values such as intraclass correlation coefficient (ICC) and kappa statistic are used to quantify reliability, translation of this information in to clinical practice remains unclear. Minimal detectable change (MDC) provides a means to translate the reliability of an outcome measure in to clinical practice, making the information more meaningful to the clinician. MDC is defined as the smallest real change that falls outside the measurement error.^{15,16} MDC is required to distinguish between a true performance change and a change due to measurement error.^{15,16} Lower MDC values ascertain higher reliability of a measure. At this time, there is a lack of MDC data on the various postural control outcome measures in typically developing children.

The objectives of this review were to 1) report the test-retest, intra-rater and inter-rater reliability of postural control outcome measures, to 2) report the minimal detectable change and standard error of measurement (SEM) of these outcome measures and to 3) describe methodological and reporting qualities of the studies that examined the reliability of postural control outcome measures in typically developing children with a mean age of 8-18 years.

Methods

Search strategy

An electronic search of PubMed and CINAHL was performed for literature published between 1985 until February, 2018 using search terms including “balance OR standing OR equilibrium OR walking OR postural control OR postural stability OR postural sway OR steadiness AND children OR child OR toddler OR pediatric OR pre-pubertal OR young OR youth OR kid OR young children OR school aged OR adolescent AND reliability OR responsiveness OR validity OR development OR validation”. The search was further supplemented by manual search of the references of articles that were initially selected.

Study selection

Studies in this review were included if they met the following inclusion criteria: 1) published in the English language, 2) examined the reliability of static and/or dynamic postural control outcome measures of typically developing children or adolescents with mean age between 8-18 years. Studies were excluded if they met at least one of the following criteria 1) the mean age over 18 or below 8 years, 2) participants with neuromuscular, musculoskeletal or cardiopulmonary impairments or conditions that may have impacted performance (e.g. history of recent concussion), 3) any grey literature including reports, dissertations, non-peer reviewed publications, conference proceedings, non-commercial translations and bibliographies as these often lack sufficient details required for data extraction and assessment of methodological and reporting quality.

Data extraction

Two independent reviewers (DT and CT) reviewed titles and abstracts. The same two reviewers independently performed data extraction for each study included in the review. Participants' age group, sample size and gender were extracted from the studies for descriptive purposes. Types of reliability assessed, reliability coefficients (e.g. ICC, Pearson's/ Spearman's r, Kappa statistics), confidence intervals and test-retest intervals were also extracted. For Intraclass correlation coefficients, the models (one-way random (model 1), two-way random (model 2) and two-way mixed (model 3)), and forms (single measures (1) or averaged (k) measures) were extracted whenever specified. All ICCs and confidence intervals reported within a valid range from 0 to 1 were reported. The ICCs with values above 0.75 were interpreted as demonstrating good reliability, 0.50 and 0.75 as moderate reliability and coefficients below 0.50 indicating poor reliability.¹⁵

Due to lack of specific guidelines for interpretation of the Pearson's "r" and Spearman's rho for reliability analysis, these values were interpreted following the same guidelines as reported for ICC described by Portney & Watkins.¹⁵ MDC values and SEM scores were also extracted from studies whenever reported. When the MDC and SEM were not reported, these values were calculated from the available information on ICC for the test-retest reliability and initial standard deviation. SEM was calculated using the formula $SEM = \text{Standard deviation} \times \sqrt{1-ICC}$. Using this SEM value, MDC was calculated as $SEM \times \sqrt{2} \times 1.96$.¹⁵

Data classification and interpretation

Owing to the variable nomenclature of postural control, postural control measures were classified according to the construct they assessed, i.e. static or dynamic. Operationally, static

postural control was defined as “the ability to maintain postural control in upright standing while standing still”¹⁷ whereas dynamic postural control was defined as “ability to maintain postural control during functional movements such as reaching and walking.”¹⁸ If a measure contained both static and dynamic postural control items, then the measure was reported under both static and dynamic postural control sections. Static and dynamic postural control measures were further classified as instrumented and non-instrumented.

Assessment of reporting and methodological quality

The same two reviewers (DT & CT) rated the studies for quality of reporting as well as methodological quality. The reporting quality was assessed using the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) checklist,¹⁹ whereas the methodological quality was assessed using the Quality Appraisal for Reliability Studies (QAREL) statement.²⁰ The STROBE checklist includes 22 items addressing different aspects of reporting in observational studies.¹⁹ Each item on the STROBE was rated with a yes or no response and was assigned a numerical value of 0 or 1 respectively with a maximum total score of 22. Higher scores indicated better reporting quality. QAREL is an 11 item tool including seven major domains addressing various aspects of the methodological quality such as blinding, subjects, assessors, use of appropriate statistics, sample representation, order of examination and suitability of time interval between repeated measurements, with higher scores indicating better methodological quality.²⁰ Similar to the STROBE, the items on the QAREL were rated as 0 or 1, with higher scores indicating better methodological quality. Any disagreement between the two reviewers was resolved by mutual consensus. If disagreement remained, a third reviewer (BA) was consulted. Inter-rater reliability among the reviewers was tested using the ICC and was found to be good ($ICC_{3,1} = 0.98$, 95% CI = 0.95-0.99)

Results

Initial Yield

The electronic search yielded 5,820 studies with 19 additional studies that were found via manual search of references. After removing of duplicates (n=16) and exclusion of studies by reviewing titles and abstract (n=5743), 80 studies were included for full-text reviews. Following a review of full-texts, twenty-five 25 studies that were included in the final qualitative analysis. ([Appendix II A](#)). The reasons for excluding studies after full text review (n=55) are detailed in Figure 1 and [Appendix II B](#).

Insert figure 1 about here

Quality of studies

The studies included in this review demonstrated high variability in quality of reporting as indicated by the STROBE scores that ranged from 13-22 out of 22 with a median score of 20. Out of the twenty-two items on the STROBE statement, sample size calculation, limitations of the study and measures to control bias were the least reported items ([Appendix II B](#)). QAREL scores ranged between 8-11, with lowest scores observed for items 1 (representative sample) and 8 (order of examination). ([Appendix II C](#)).

Characteristics of included studies

Twenty-two different postural control measures were identified from the 25 studies included in the final review. These 22 measures represented 8 static and 14 dynamic measures.

Eleven studies examined static postural control measures, 11 studies examined dynamic postural control measures, and 3 studies examined both static and dynamic measures.

Static postural control measures comprised of both instrumented and non-instrumented measures. Instrumented measures included the Balance Error Scoring System (BESS), Clinical Test of Sensory Interaction in Balance (CTSIB) using SVeP stabilometric platform, Neurocom balance master (BM) and AccuGait, Laboratory System and Clinical System (lab sys & clin sys), Limits of Stability (LOS), single leg stance (SLS) and tandem stance. The non-instrumented measures included the original BESS, modified BESS, single leg mini squat test, SLS and Zurich Neuromotor Assessment (ZNA). Of all the static postural control measures, BESS was the most commonly examined measure (6 studies),²¹⁻²⁶ followed by CTSIB (3 studies),²⁷⁻²⁹ LOS (2 studies),^{28,30} and SLS (2 studies).^{29,31} Other measures included tandem stance,²⁹ ZNA,³² lab sys & clin sys,³³ and single leg mini squat test,³⁴ (1 study per outcome measure). ([Table II.1](#))

The dynamic measures comprised of both individual measures and test batteries. Individual measures included the balance beam walk, Five Times Sit to Stand (FTSTS), Functional Reach Test (FRT), modified FRT, one leg hop, Standardized Walking Obstacle Course (SWOC), Star Excursion Balance Test (SEBT), Timed Up and Down Stairs (TUDS) and Timed Up and Go (TUG) ([Table II.1](#)). Test batteries included were the Balance Evaluation Systems Test (BEST), mini BEST, Dynamic Gait Index (DGI), mini BEST, Movement Assessment Battery (MAB) and ZNA. Among the dynamic postural control measures, the TUG was most commonly examined (3 studies),^{21,35,36} followed by FRT,^{37,38} and SEBT.^{39,40} Balance beam walk,²⁹ FTSTS,²¹ mFRT,³⁵ one leg hop,²⁹ SWOC,⁴¹ TUDS,⁴² BEST,⁴³ mini BEST,⁴³ DGI,⁴⁴ MAB,⁴⁵ and ZNA,³² were examined in separate single studies ([Table II.2](#)).

The sample size of the included studies was largely variable (9 - 459 participants). Variable representation from both genders was noted, with one study including only female participants³⁷ and four studies with missing information on gender distribution^{22,25,33,40} ([Table II. 2](#) and [Table II.3](#)).

Reliability types and outcomes

Test-retest reliability was the most commonly examined type of reliability (20 studies) followed by inter-rater (10 studies) and intra-rater reliability (9 studies). High variability was observed in the test-retest intervals ranging from 15 minutes to 60 days from the first test.

Twenty-four studies examined reliability using the Intraclass correlation coefficient (ICC). Nine studies utilized two-way random model with single measures (ICC_{2,1}),^{23,30,33,37,41,42,44,45} four studies utilized two-way mixed model with single measure (ICC_{3,1}),^{21,24,31,39} one study utilized two-way mixed model with two-way mixed model with average measures (ICC_{3,2}),⁴¹ and two studies utilized one-way random model with single measures (ICC_{1,1}).^{35,38} Specifications on the model and/or form of the ICC used was not provided in nine studies.^{22,25,27-29,32,36,40,43} Percent agreement⁴⁴ and linear weighted kappa³⁴ were used in one study each.

Overall, MDC scores were available for 16 outcome measures (6 static, 10 dynamic). MDC was reported in five studies^{21,24,30,39,43} and was calculated using SEM values^{26,29,33,35,36,38} and/or standard deviations^{28,44} in 8 studies. The MDC for the TUG was the most documented (3 studies)^{21,35,36} followed by BESS (2 studies),^{24,26} and LOS.^{28,30}

Static postural control

The test-retest reliability for the CTSIB across various force platforms was examined under four conditions, including eyes open (EO) and eyes closed (EC) on firm and foam surfaces for sway velocity and sway area. Sway area demonstrated lower reliability scores as compared to sway velocity for all force platforms. Of these, CTSIB with the AccuGait force plate demonstrated highest test retest reliability across all 4 test conditions (ICC = 0.72-0.91, CI = 0.54-0.95) for sway velocity.²⁹ Test retest reliability scores were comparable between AccuGait and stabilometric platform posturography (ICC = 0.48-0.65, CI = 0.21-0.79) for sway area.^{27,29} Tandem stance on AccuGait also demonstrated good test-retest reliability both in EO and EC conditions (ICC = 0.83-0.87).²⁹

The LOS demonstrated highest test-retest reliability scores in the 14-18-year age group (ICC = 0.73-0.96) with end-point excursion and maximum excursion as the most reliable parameters.³⁰ The instrumented BESS also demonstrated moderate test-retest reliability scores (ICC = 0.74, CI = 0.5-0.87).²⁴ Clin sys & lab sys, on the other hand, demonstrated lowest test-retest reliability. Poor to good reliability values were observed for SLS across different force platforms ([Table II.2](#)).

Among the non-instrumented static postural control measures, BESS and modified BESS demonstrated highest test-retest reliability values (ICC = 0.6-0.74 & 0.73 respectively).^{22,24} Test-retest reliability for SLS ranged from ICC of 0.46-0.86, with higher reliability scores noted for EO condition.^{29,31} The BESS and the ZNA tests both demonstrated high inter-rater reliability (ICC = 0.95 and 0.98 respectively)^{23,32} The single leg mini squat test demonstrated moderate to

good inter-rater reliability (Linear weighted kappa = 0.54-0.86).³⁴ The intra rater reliability was found to be highest for the ZNA (ICC = 1.0) followed closely by the BESS (ICC = 0.99).^{23,25,32}

Of all the available static postural control measures, BESS, CTSIB, LOS, SLS, tandem stance and lab sys & clin sys had available MDC values. For these measures, the MDC values were reported in 2 studies (BESS²⁴ and LOS³⁰) and were computed from the data available in 4 studies (BESS,²⁶ LOS,²⁸ CTSIB,²⁹ SLS,²⁹ tandem stance²⁹ and lab sys & clin sys,³³). The MDC of LOS ranged from 0.1-0.3 seconds for reaction time, and 1.5-3.4 degrees per second for movement velocity, with smaller values noted for older age groups. For the BESS, MDC values were available for both instrumented and non- instrumented versions (instrumented = 0.6 degrees/second; non-instrumented = 9.1 errors). Details on MDC and SEM values are reported in [Table II.4](#).

Dynamic postural control

Among the individual dynamic postural control measures, modified FRT and one leg hop demonstrated highest test-retest reliability values (ICC = 0.95 (0.91-0.99); 0.95 (0.91-0.97) respectively)^{29,35} followed by FTSTS,²¹ TUDS,⁴² balance beam and TUG.^{21,35,36} The SEBT demonstrated moderate to good test-retest reliability (ICC = 0.53-0.93) with highest reliability observed for posterolateral direction.³⁹ Among test batteries, both BEST and mini BEST demonstrated moderate to good test-retest reliability scores.⁴³ On the other hand, reliability scores were found to have high variability for measures including the FRT, DGI and MAB ([Table II.3](#)). Test-retest reliability was not available for SWOC and MAB.

The SWOC, ZNA, DGI and BEST demonstrated good inter-rater reliability (ICC = 0.99; ICC = 0.96 – 0.99; ICC = 0.90; percent agreement = 90 and ICC = 0.87). Both ZNA and BEST

demonstrated good intra-rater reliability ($ICC = 1.0$ and 0.96 respectively).^{32,43} Dynamic postural control component of ZNA demonstrated good reliability in all three forms ($ICC = 0.86-1.0$).³² Balance component of MAB demonstrated high test-retest reliability ($ICC = 0.84-0.91$) but poor to moderate inter-rater ($ICC = 0-0.58$) and intra-rater ($ICC = 0.15-0.72$) reliability.⁴⁶

Of the available dynamic postural control measures, MDC values were available for the TUG, mFRT, FRT, FTSTS, BEST, miniBEST, SEBT and DGI. Out of these, the MDC values were reported in 3 studies (SEBT,³⁹ BEST,⁴³ miniBEST,⁴³ FTSST²¹ and TUG²¹) and were calculated from 5 studies (mFRT,³⁵ FRT,³⁸ TUG^{35,36} one leg hop,²⁹ balance beam walk,²⁹ and DGI,⁴⁴). For TUG scores, MDC values ranged from 0.6-0.9 seconds. The MDC for FRT ranged from 7.1 to 9.8 centimeters (cm) as compared to 3.9 cm for the mFRT. The MDC values for BEST and miniBEST were calculated both in real time and video settings. For real time, the values were 1.3 points for miniBEST and 6.6 for BEST whereas for video the values were 2.4 for miniBEST and 4.9 for the BEST. Details on the MDC and SEM values are reported in [table II.4](#).

Discussion

The purpose of this systematic review was to provide a comprehensive overview of measurement error of static and dynamic postural control measures in typically developing children. To the author's knowledge, this is the first systematic review that reported measurement error of static and dynamic postural control measures in typically developing children. This review describes the absolute and relative reliabilities, and MDC values in the typically developing children for various available static and dynamic postural control measures as well as the assessment of methodological quality and clarity of reporting in the included studies. Evaluation of the methodological quality of a study is important to determine if the findings of the study are to be considered generalizable. By providing a comprehensive description of the reliability, MDC and study quality, this review will aid the clinician user in making informed decisions when selecting an outcome measure.

Results of this study indicate that instrumented measures such as AccuGait, and non-instrumented measures such as BESS and TUG demonstrated highest reliability scores and may prove useful for evaluation of static and dynamic postural control in the clinical settings respectively.

Static Postural Control Measures

Both instrumented and non-instrumented versions of the BESS demonstrated comparable reliability despite previous research suggesting that higher sensitivity of the instrumented BESS in recording minor non-meaningful changes may result in increased error thereby lowering the reliability scores.³⁰ This warrants a need for further exploration of the clinical utility of the instrumented BESS in terms of cost effectiveness in this population.

A comparison of different force platforms to evaluate CTSIB revealed highest reliability for the AccuGait force platform. Better performance of the AccuGait may be explained by the fact that the test results are not affected by foot positioning on the force platform as is true with the other measures.^{28,29} In contrast, the Neurocom BM appears to have a higher potential for errors as the protocol for measuring stability requires the exact same foot positioning on the force plate.²⁸ In terms of specific parameters, it was observed that sway velocity was a better measure as compared to sway area for reliability.

Higher reliability of the LOS in the older age groups (≥ 14 years) could be explained by the fact that postural control in children does not reach the adult level by the age of 13-14 years. Reliability values were also noted to change with the number of trials, and test-retest intervals. LOS appeared to demonstrate higher reliability when one practice trial was given instead of multiple practice trials before recording the data,^{28,30} which could be attributed to the onset of fatigue with multiple trials prior to the test resulting in lower reliability. Emery et al noted that using a test-retest interval of 1 week could affect the reliability by allowing time to practice balance and from the possible effect of other physical activities on balance during this interval.³¹

Other static postural control measures such as SLS and ZNA on the other hand demonstrated variability in their performance in terms of reliability.^{31,32} The ZNA utilized occurrence of first failure to characterize performance instead of a mean of trials which may have resulted in errors.³² Variability in performance for these measures could also be attributed to personal differences including attention span, concentration and motivation levels. Baker et al postulated that variability in static postural control measurements could be due to individual variability in the utilization of visual, vestibular and proprioceptive inputs in maintaining postural control.³³ However, single study findings limit the generalizability of the results.

Dynamic postural control measures

Among the dynamic measures, the TUG.^{35,36} was most widely studied and demonstrated good test-retest reliability. Other measures including modified FRT, one leg hop, FTSTS,²¹ TUDS,⁴² demonstrated high reliability, however were reported only in single studies, indicating a need for further research. The ease of administration, simplicity of instructions and brevity of TUG could explain its higher reliability. In addition, minimal equipment, time and practice requirements could have contributed in providing stable results.³⁵ The FRT demonstrated good reliability values in 15-16-year age group as compared to younger age groups. This variation in reliability could be explained by differences in concentration, motivation and fatigue as well as higher variation in postural control development in the younger age groups.^{37,38} The difference in the reliability values between mFRT and FRT could be explained by the smaller number of practice trials and longer rest intervals between trials during mFRT.³⁵ Additionally, mFRT demonstrated a smaller MDC (3.9 cm) as compared to FRT (7-9.8 cm) indicating the possibility of better clinical applicability in children and adolescents. However, single study observations on mFRT limit the strength of the findings. Similarly, despite moderate to good reliability scores on the SEBT (ICC = 0.51-0.93), ZNA (ICC = 0.86) and TUDS (ICC = 0.94), single study observations and lack of confidence intervals warrant cautious interpretation of findings.

Among test batteries, both BESTest versions demonstrated moderate to good agreement over days⁴³ indicating that both versions may be appropriate to be used for monitoring of postural control development in children over time. The DGI on the other hand, demonstrated wide confidence interval in the test-retest reliability scores. A possible explanation for this finding may be that the instructions for individual DGI items were difficult for children to understand and appeared to increase the cognitive load. The authors have recommended

modifications to the DGI items to make it suitable for pediatric population.⁴⁴ The ZNA and BESTest also demonstrated good inter and intra-rater reliability in addition to good test-retest reliability scores. However, single study findings warrant cautious interpretation of these findings and highlight need for further research.

The findings of this review indicated methodological inconsistencies in the studies evaluating reliability of postural control measures. Diversity was observed in the age range and sample size reported across various studies that were included in this review. Four out of eight static and 11 out of 14 dynamic measures were reported in single studies thereby warranting further research in typically developing population ([Table II.2](#) and [Table II.3](#)). Sample size calculation has been identified as an essential component of reporting in reliability studies in order to achieve a specified width of confidence interval.⁴⁷ Eighty four percent of the studies did not report methods that were used to calculate sample size, thereby making the generalizability of their results questionable. There is a need for use of more robust statistical tests for power analysis. Hence, the lack in the quality and quantity of studies makes it difficult to generalize the reliability of these measures.

Confidence intervals (CI) provide estimates of reliability for any outcome measure with narrower CI indicating better reliability.⁴⁸ This review revealed that CI was not reported in twelve out of 25 studies. Also, inconsistencies in reliability coefficients, type and model of ICC used further contributed to limited generalizability of these results. Use of ICC has been reported to decrease systematic error and also to account for performance consistency between tests over time.¹⁵ In spite of a consensus regarding use of ICC as a measure of reliability, variations in models and forms of ICCs may yield considerably different ICC values.⁴⁹ Also, 36 % (9 out of

25) did not report information on model and type of ICC, which may have affected the overall range of reliability coefficients reported in the reviewed studies.

In addition to measuring the relative reliability of instruments, the assessment of absolute reliability is needed to evaluate the response stability of a measure.¹⁵ Whereas relative reliability can be measured with statistical measures such as ICC, absolute reliability involves measurement of MDC and SEM.⁵⁰ MDC might be considered as an estimation of an outcome measure's ability to detect true change and is often considered a more meaningful tool in clinical practice.⁵¹ However, this review found that MDC was only reported in five studies. Additionally, for the measures that had MDC values, the scores could not be compared due to methodological differences and limited number of studies. Therefore, future reliability studies should also include measurement of MDC and SEM, given that the postural control measures are generally used to examine postural control over time to evaluate response to an intervention.

This review provides details on the reliability and MDC of postural control measures in typically developing children. The results from this review, recommend cautious use of BESS for static and TUG for dynamic postural control assessment. Several other dynamic postural control measures demonstrated promising results but further investigation is warranted. Diversity existed among the studies in terms of reliability calculation and reporting, thereby limiting generalizability of the findings. Additionally, it is essential to consider other measurement properties including various forms of validity and responsiveness while making informed decision about selection of an outcome measure.

The findings of this review suggest that a wide variety of clinical measures is available for assessment of postural control. However, most of these measures have not been studied

extensively in terms of their measurement properties, thereby limiting the confidence in making strong recommendations for their clinical applicability at this time. Therefore, selection of outcome measure must depend on the purpose and specificity of task in question. It is also important to note that other measurement properties such as validity and responsiveness must be considered when making a choice of assessment tool. Outcome measures with excellent reliability will not be useful if these are not valid in measuring the desired construct. Finally, clinicians must be aware of the reliability of different measures when deciding on the selection of outcome measures, however, must make an informed decision based on information gathered from multiple assessments, and not just rely on one measure.

Limitations

The heterogeneity in the sample studied and limited number of studies assessing reliability in different age groups contributed to the limitations of this review. Lack of reporting of power analysis and confidence intervals, inconsistencies in the use of appropriate reliability coefficients and limitations in methodological quality of the studies limit the findings of this review. Hence, caution is advised when interpreting the findings.

Conclusion

The findings of this review suggest that among the static postural control measures, BESS demonstrates acceptable reliability across studies and may be used for evaluation of static postural control in typically developing children. The CTSIB may provide reliable data when used with the AccuGait force platform. Among the dynamic postural control measures, TUG demonstrated good reliability and can be used cautiously to evaluate dynamic postural control. Other measures including the mFRT, one leg hop, BEST and mini BEST provide promising findings. However, single study observations and methodological inconsistencies warrant cautious interpretation of findings. Studies with stronger methodological design in future are needed to draw meaningful conclusions.

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Figure 1: PRISMA Flow Diagram

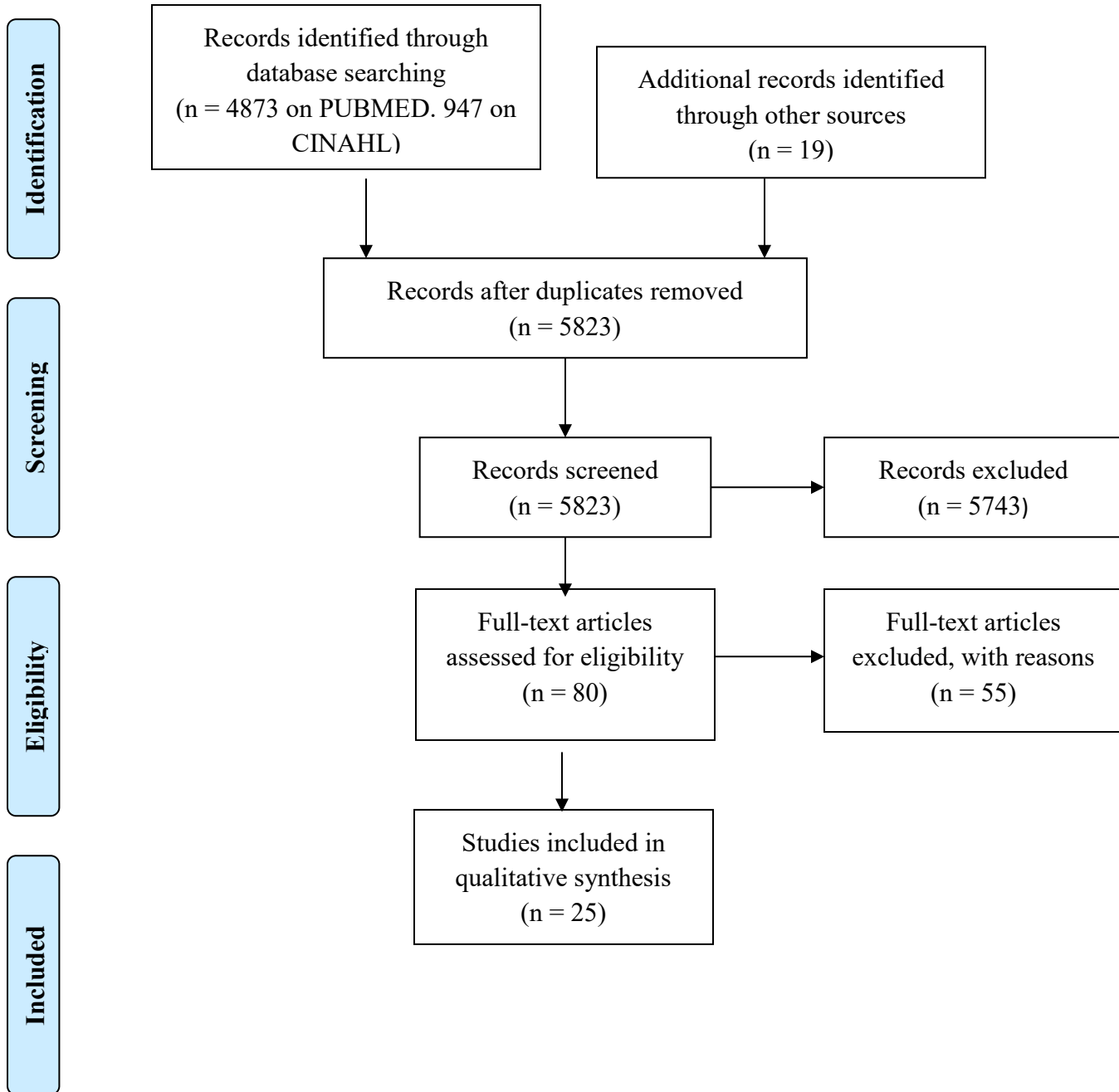


Table II.1: Classification of postural control measures

Outcome measure	Number of studies	Citations	Reported reliability types			Minimal detectable change available (Y/N)
Static postural control						
			Inter-rater	Intra-rater	Test-retest	
Balance error scoring system	6	Alsalaheen, ²¹ Alsalaheen, ²⁴ Hunt, ²² Khanna, ²⁵ McLeod, ²³ McLeod ²⁶	Y ²¹	Y ^{23,25}	Y ^{22,24,26a}	Y ^{24,26}
Clinical system & laboratory system	1	Baker ³³	N	N	Y ³³	Y ³³
Clinical test of sensory interaction in balance	3; (4 instrumented measures)	Barozzi, ²⁷ DeKegel, ²⁹ Geldhof, ²⁸	N	N	Y ^{27-29a}	Y ²⁹
Limits of stability	2	Alsalaheen, ³⁰ Geldhof, ²⁸	N	N	Y ^{28,30}	Y ^{28,30}
Single leg stance	2; (2 instrumented & 2 clinical)	DeKegel, ²⁹ Emery, ³¹	N	N	Y ^{29,31a}	Y ²⁹
Single leg mini squat	1	Junge, ³⁴	Y ³⁴	N	N	NA
Tandem stance	1	DeKegel, ²⁹	N	N	Y ²⁹	Y ²⁹
Zurich neuromotor assessment	1	Rousson, ³²	Y ³²	Y ³²	Y ^{32a}	N
Dynamic postural control						
Balance beam walk	1	DeKegel, ²⁹	N	N	Y ²⁹	Y ²⁹
Five times sit to stand	1	Alsalaheen, ²¹	N	N	Y ²¹	Y ²¹
Functional reach test	2	Donahoe, ³⁷ Volkmann, ³⁸	Y ³⁷	Y ³⁷	Y ^{37,38a}	Y ³⁸
Modified functional reach test	1	Leurer, ³⁵	N	N	Y ³⁵	Y ³⁵
One leg hop	1	DeKegel, ²⁹	N	N	Y ²⁹	Y ²⁹
Standardized walking obstacle course	1	Held, ⁴¹	Y ⁴¹	Y ⁴¹	N	N
Star excursion balance test	2	Calatayud, ³⁹ Shaikh, ⁴⁰	Y ⁴⁰	Y ⁴⁰	Y ³⁹	Y ³⁹
Timed up & down stairs	1	Zaino, ⁴²	Y ⁴²	Y ⁴²	Y ^{42a}	N
Timed up & go test	3	Alsalaheen, ²¹ Leurer, ³⁵ Panisson, ³⁶	N	N	Y ^{21,35,36}	Y ^{21,35,36}
Balance evaluation systems test	1	Dewar, ⁴³	Y ⁴³	Y ⁴³	Y ⁴³	Y ⁴³
Dynamic gait index	1	Vilnai, ⁴⁴	Y ⁴⁴	N	Y ⁴⁴	Y ⁴⁴

Mini balance evaluation systems test	1	Dewar, ⁴³	Y ⁴³	Y ⁴³	Y ⁴³	Y ⁴³
Movement assessment battery	1	Holm, ⁴⁵	Y ⁴⁵	Y ⁴⁵	N	N
Zurich neuromotor assessment	1	Rousson, ³²	Y ³²	Y ³²	Y ^{32a}	N

Abbreviations: ^a = MDC from this study could not be calculated due to non-reported variables (Reference #: 5,9,10,11,14,21, 25)

Table II.2: Reliability coefficients for static postural control measures

Outcome measure	Type of reliability	Reliability coefficient (Confidence interval)		Author	Age group in years, Sample size (% of males)	
Balance error scoring system	Inter-rater	ICC _(3,1) = 0.95(NS)		Alsalaheen et al. ²¹	14-18 N = 91(51.6)	
	Intra rater	ICC _(NS) = 0.99(NS)		Khanna et al. ²⁵	10-17 N = 30(NS)	
		ICC _(2,1) = 0.98(NS)		McLeod et al. ²³	9-14 N = 50(48)	
	Test-retest	Original: ICC _(3,1) = 0.74(0.48-0.88) Instrumented: ICC _(3,1) = 0.74(0.5-0.87)		Alsalaheen et al. ²⁴	14-18 N = 36(47)	
		Modified: ICC _(NS) = 0.73(NS) Original: ICC _(NS) = 0.6(NS)		Hunt et al. ²²	13-19 N = 222(NS)	
		ICC _(2,1) = 0.7(NS)		McLeod et al. ²⁶	9-14 N = 50(48)	
Clinical system & laboratory system	Test-retest	Clinical system: ICC _(2,1) = 0.3(NS) Laboratory system: ICC _(2,1) = 0.3(NS)		Baker et al. ³³	8-12 N = 9(NS)	
Clinical test of sensory interaction in balance	Test-retest	SVeP stabilometric platform: ICC _(NS)			Barozzi et al. ²⁷	6-14 N=289(60)
			Sway velocity (deg/sec)	Sway area (cm ²)		
		Eyes open	0.75(0.65-0.78)	0.57(0.48-0.64)		
		Eyes closed	0.76(0.7-0.8)	0.61(0.53-0.68)		
		Pad eyes open	0.75(0.7-0.8)	0.5(0.41-0.58)		
		Pad eyes closed	0.72(0.65-0.77)	0.55(0.47-0.63)		
	Test-retest	AccuGait: ICC _(NS)			DeKegel et al. ²⁹	6 – 12 N = 49(55)
			Sway velocity (deg/sec)	Sway area (cm ²)		
		Eyes open	0.81(0.67-0.89)	0.48(.21-0.69)		
		Eyes closed	0.91(0.84-0.95)	0.63(0.4-0.79)		
		Pad eyes open	0.85(0.74-0.91)	0.55(0.3-0.73)		
		Pad eyes closed	0.72(0.54-0.84)	0.65(0.44-0.79)		
	Test-retest	Neurocom balance master: ICC _(NS)			Geldhof et al. ²⁸	9-10 N=20(50)
			Sway velocity (deg/sec)			
		Eyes open	0.59(0.21-0.82)			
		Pad eyes open	0.68(0.35-0.87)			
		Eyes closed	0.37(0.09-0.9)			
		Pad eyes closed	0.63(0.33-0.87)			
		Composite	0.77(0.47-0.91)			
			Sway velocity (deg/sec)		DeKegel et al. ²⁹	6 – 12 N = 49(55)
		Eyes open	0.68(0.5-0.8)			
Pad eyes open		0.65(0.45-0.79)				
Eyes closed		0.85(0.75-0.91)				
Pad eyes closed		0.49(0.25-0.68)				
Composite		NS				

Limits of stability	Test-retest	Neurcom balance master: ICC (NS,1)		Geldhof et al. ²⁸	9-10 N=20(50)	
		Reaction time (sec)	0.4 (0-0.71)			
		Movement velocity (deg/sec)	0.46 (0.3-0.74)			
		End point excursion (% LOS)	0.62 (0.23-0.82)			
		Maximum excursion (% LOS)	0.46 (0.04-0.75)			
		Directional control (%)	0.44 (0.04-0.71)			
		Reaction time (sec)	0.81 (0.45-0.94)	Alsalaheen et al. ³⁰	14-18 N = 36(47)	
		Movement velocity (deg/sec)	0.89 (0.66-0.96)			
		End point excursion (% LOS)	0.96 (0.88-0.99)			
		Maximum excursion (% LOS)	0.95 (0.84-0.98)			
		Directional control (%)	0.73 (0.18-0.91)			
		Composite	NS (0.73-0.96)			
Single leg stance	Test-retest	Clinical: ICC (NS)		DeKegel et al. ²⁹	6-12 N=49(55)	
		Eyes open	0.83(0.71-0.90)			
		Eyes closed	0.86(0.77-0.92)			
		Clinical: ICC (3,1)		Emery et al. ³¹	16-17 N=111(50.5)	
		Eyes open	NA			
		Pad eyes open	0.59 (0.43-0.71)			
		Eyes closed	0.69 (0.57-0.73)			
		Pad eyes closed	0.46 (0.31-0.59)			
		AccuGait: ICC (NS)		DeKegel et al. ²⁹	6-12 N=49(55)	
			Sway velocity (cm/sec)			Sway area (cm ²)
		Eyes open	0.86(0.75-0.93)			0.73(0.54-0.85)
		Eyes closed	0.21(0-0.6)			0.21(0-0.61)
		Neurocom balance master: ICC (NS)		DeKegel et al. ²⁹	6-12 N=49(55)	
			Sway velocity (deg/sec)			
		Eyes open	0.59(0.35-.076)			
		Eyes closed	0.11(0-0.52)			
Single leg mini squat	Inter-rater	Linear weighted kappa = 0.54-0.86 (NS)		Junge et al. ³⁴	9-10, 12-14 N=74(51.3)	
Tandem stance	Test-retest	AccuGait: ICC (NS)		DeKegel et al. ²⁹	6-12 N=49(55)	
			Sway velocity (cm/sec)			Sway area (cm ²)
		Eyes open	0.87(0.77-0.93)			0.81(0.66-0.90)
		Eyes closed	0.83(0.66-0.92)			0.64(0.36-0.82)
Zurich neuromotor assessment	Inter-rater	ICC (NS) = 0.98 (NS)		Rousson et al. ³²	6-12 N=30(40)	
	Intra-rater	ICC (NS) = 1.0 (NS)				
	Test-retest	ICC (NS) = 0.57 (NS)			7-10 N=56(44.6)	

Abbreviations: ICC = Intraclass correlation coefficient, cm = centimeters, sec = seconds, deg = degrees, NS = not specified

Table II. 3: Reliability coefficients for dynamic postural control measures

Outcome measure	Type of reliability	Reliability coefficient (Confidence interval)	Author	Age group in years, Sample size (% of males)
Balance beam walk	Test-retest	ICC _(NS) = 0.88 (0.79-0.93)	DeKegel et al. ²⁹	6-12 N=49(55)
Balance evaluation systems test	Inter-rater	ICC _(NS) = 0.87 (0.79-0.95)	Dewar et al. ⁴³	7-17 N=34(56)
	Intra-rater	ICC _(NS) = 0.96 (0.93-0.99)		
	Test-retest	ICC _(NS) = 0.82-0.84 (0.69-0.96)		
Dynamic gait index	Inter-rater	% agreement = 90	Vilnai et al. ⁴⁴	8-15 N=10(80)
	Test-retest	ICC _(2,1) = 0.71 (0.26-0.91)		
Five times sit to stand	Test-retest	ICC _(3,1) = 0.91 (0.86-0.95)	Alsalaheen et al. ²¹	14-18 N=61(NS)
Functional reach test	Inter-rater	ICC _(2,1) = 0.98 (NS)	Donahoe et al. ³⁷	5-15 N=15(0)
	Intra-rater	ICC _(2,1) = 0.83 (0.80-0.97)		
	Test-retest	ICC _(2,1) = NS (0.64-0.75)	Volkman et al. ³⁸	7-16 N=80(50)
		7-8 yrs: ICC _(1,1) = 0.39 (0-0.7) 11-12 yrs: ICC _(2,1) = 0.59 (0.25-0.80) 15-16 yrs: ICC _(2,1) = 0.87 (0.73-0.94)		
Mini Balance evaluation systems test	Inter-rater	ICC _(NS) = 0.56 (0.33-0.79)	Dewar et al. ⁴³	7-17 N=34(56)
	Intra-rater	ICC _(NS) = 0.86 (0.78-0.95)		
	Test-retest	ICC _(NS) = 0.74-0.84 (0.55-0.96)		
Movement assessment battery	Inter-rater	Balance component: ICC _(2,1) = 0.29 (0.07-0.58) Total score: ICC _(2,1) = 0.62 (0.35-0.8)	Holm et al. ⁴⁵	8-9.5 N=45(48.8)
	Intra-rater	Balance component: ICC _(2,1) = 0.49 (0.15-0.72) Total score: ICC _(2,1) = 0.68 (0.28-0.85)		
Modified functional reach	Test-retest	Forward: ICC _(1,1) = 0.95 (0.91-0.99) Preferred: ICC _(1,1) = 0.95 (0.91-0.99) Non-preferred: ICC _(1,1) = 0.94 (0.91-0.97)	Leurer et al. ³⁵	7-14 N=24(66.6)
One leg hop	Test-retest	ICC _(NS) = 0.95 (0.91-0.97)	DeKegel et al. ²⁹	6-12 N=49(55)
Standardized walking obstacle course	Inter-rater	Time: ICC _(2,1) = 0.99 (NS) No. of Steps: ICC _(2,1) = 0.94-0.97 (NS)	Held et al. ⁴¹	3-17 N=50(46)
	Intra-rater	Time: ICC _(3,2) = 0.83-0.94 (NS) No. of Steps: ICC _(3,2) = 0.84-0.94 (NS)		
Star excursion balance test	Inter-rater	ICC _(NS) = NS (0.59-0.95)	Shaikh et al. ⁴⁰	12-16 N=200(NS)
	Intra-rater	ICC _(NS) = NS (0.68-0.95)	Calatayud et al. ³⁹	10-12 N=24(50)
	Test-retest			
		Anterior: ICC _(3,1)		
		Posteromedial: ICC _(3,1)		
Timed up & down stairs	Inter-rater	ICC _(2,1) = 0.99 (NS)	Zaino et al. ⁴²	8-14 N=27(48.1)
	Intra-rater	ICC _(2,1) = 0.99 (NS)		
	Test-retest	ICC _(2,1) = 0.94 (NS)		
Timed up & go	Test-retest	ICC _(3,1) = 0.84 (0.75-0.90)	Alsalaheen et al. ²¹	14-18 N=61(NS)
		ICC _(1,1) = 0.85 (0.74-0.92)	Leurer et al. ³⁵	7-14 N=24(66.6)
		ICC _(NS) = 0.93-0.95 (NS)	Panisson et al. ³⁶	3-18 N=459(49.4)
Zurich neuromotor assessment	Inter-rater	ICC _(NS) = 0.90 (NS)	Rousson et al. ³²	6-12 N=30(40)
	Intra-rater	ICC _(NS) = 1.0 (NS)		7-10 N=56(44.6)
	Test-retest	ICC _(NS) = 0.90 (NS)		

Abbreviations: ICC = Intraclass correlation coefficient, cm = centimeters, NS = not specified, No. = number

Table II.4: Minimal detectable change (MDC-95) and standard error of measurement (SEM) for postural control measures

Test	Author	Age (yrs)	MDC-95 (SEM)		
Static postural control					
Balance error scoring system (instrumented)	Alsalaheen et al. ^{24a}	14-18	Averaged score (deg/sec): 0.6(0.2)		
	McLeod et al. ^{26 b}	9-14	9.1(3.3)		
Clinical test of sensory interaction in balance	DeKegel et al. ^{29 b}	6-12	AccuGait		
				Sway velocity (cm/s)	Sway area (cm ²)
			Eyes open	0.6(0.2)	5.1(1.8)
			Pad eyes open	0.8(0.3)	8.5(3.1)
			Eyes closed	0.6(0.2)	4.6(1.7)
			Pad eyes closed	1.4(0.5)	18.2(6.6)
			Neurocom balance master		
	DeKegel et al. ^{29 b}	6-12		Sway velocity (deg/s)	
			Eyes open	0.4(0.2)	
			Pad eyes open	0.7(0.3)	
			Eyes closed	0.3(0.1)	
			Pad eyes closed	1.1(0.4)	
Clinical system & laboratory system	Baker et al. ^{33 b}	8-12	Sway index (cm)		
			Laboratory system = 0.3(0.1)		
			Clinical system = 0.3(0.1)		
Limits of stability	Alsalaheen et al. ^{30a}	14-18	Reaction time (sec)	0.1(0.05)	
			Movement velocity (deg/sec)	1.6(0.6)	
			End point excursion (% LOS)	6.1(2.2)	
			Maximum excursion (% LOS)	5.9(2.1)	
			Directional control (%)	10.1(3.6)	
	Geldhof et al. ^{28 b}	9-10	Reaction time (sec)	0.3(0.1) *	
			Movement velocity (deg/sec)	3.3(1.2) *	
			End point excursion (% LOS)	24.4(8.8) *	
			Maximum excursion (% LOS)	21.5(7.7) *	
			Directional control (%)	17.7(6.4) *	
			Neurocom balance master		
				Sway velocity (deg/sec)	
			Eyes open	0.8(0.3)	
			Eyes closed	1.3(0.5)	
			AccuGait		
				Sway velocity (cm/sec)	Sway area (cm ²)
			Tandem eyes open	1.7(0.6)	2.7(1.0)
			Tandem eyes closed	10.8(3.9)	24.6(8.9)
			Single leg eyes open	1.4(0.5)	5.8(2.1)
			Single leg eyes closed	8.0(2.9)	49.3(17.8)
				DeKegel et al. ^{29 b}	6-12
Sway velocity (deg/sec)					

Single leg stance/ tandem stance			Eyes open	0.8(0.3)	
			Eyes closed	1.3(0.5)	
			AccuGait		
				Sway velocity (cm/sec)	Sway area (cm²)
			Tandem eyes open	1.7(0.6)	2.7(1.0)
			Tandem eyes closed	10.8(3.9)	24.8(8.9)
			Single leg eyes open	1.4(0.5)	5.9(2.1)
			Single leg eyes closed	8.2(2.9)	49.3(17.8)
Dynamic postural control					
Balance beam walk	DeKegel et al. ^{29 b}	6-12	18.62(6.74) [‡]		
Balance evaluation systems test	Dewar et al. ^{43a}	7-17	Real time: 6.6(2.4) Video: 4.9(1.8)		
Dynamic gait index	Vilnai et al. ^{44 b}	9.5-14.5	1.6(0.6) *		
Five times sit to stand	Alsalaheen et al. ^{21a}	14-18	0.4(0.1) sec		
Functional reach test	Volkmann et al. ^{38 b}	7-16	7-8 y = 9.6(3.5) [#]		
			11-12 y = 9(3.25) [#]		
			15-16 y = 6.9(2.5) [#]		
Mini balance evaluation systems test	Dewar et al. ^{43a}	7-17	Real time = 1.3(0.5) Video = 2.4(0.9)		
Modified functional reach	Leurer et al. ^{35 b}	5.5-11.5	3.9(1.4) [#]		
One leg hop	DeKegel et al. ^{29 b}	6-12	11.6(4.2) [‡]		
Star excursion balance test	Calatayud et al. ^{39a}	10-12		Left	Right
			Anterior	23.2(8.4)	8.3 (3.0) [#]
			Posteromedial	34.1(12.3)	10.5 (3.8) [#]
			Posterolateral	9.9(3.6)	11.6 (4.2) [#]
Timed up & go test	Leurer et al. ^{35 b}	5.5-11.5	0.5(0.2) sec		
	Alsalaheen et al. ^{21a}	14-18	0.8(0.3) sec		
	Panisson et al. ^{36 b}	3-18	0.8(0.3) sec		

Abbreviations: deg = degrees, sec = second, cm = centimeter, [#] = Centimeters, ^{*}=composite score, [‡]= total score, NA = Not applicable, yrs = years, ^a = MDC₉₅ reported, ^b = MDC₉₅ calculated.

Appendix II A: Reasons for exclusion

Reasons for exclusion	Studies excluded
Participants outside age range considered in this study (8-18 years) (n = 24)	Ageberg et al. ⁵² Alahamari et al. ⁵³ Atwater et al. ⁵⁴ Baldini et al. ⁵⁵ Broadstone et al. ⁵⁶ Broglio et al. ⁵⁷ Butler et al. ⁵⁸ Crowe et al. ⁵⁹ DiFabio et al. ⁶⁰ DeKegel et al. ⁶¹ Ellinoudis et al. ⁴⁶ Gabriel et al. ⁶² Gribble et al. ⁶³ Kinzey et al. ⁶⁴ Kyvelidou et al. ⁶⁵ Lariviere et al. ⁶⁶ Norris et al. ⁶⁷ Park et al. ⁶⁸ Pickerill et al. ⁶⁹ Shaffer et al. ⁷⁰ Sobera et al. ⁷¹ Tavasoli et al. ⁷² Westcott et al. ⁷³ Wikstrom et al. ⁷⁴
No healthy participants (n = 6)	Bartlett et al. ⁷⁵ Hansen et al. ⁷⁶ Marchese et al. ⁷⁷ McCoy et al. ⁷⁸ Ries et al. ⁷⁹ Wang et al. ⁸⁰
No reliability analysis (n = 7)	Dietz et al. ⁸¹ Hazell et al. ⁸² Kott et al. ⁸³ Roeber et al. ⁸⁴ Roeber et al. ⁸⁵ Rosenblum et al. ⁸⁶ Tulin et al. ⁸⁷
Age range not specified (n = 3)	Darrah et al. ⁸⁸ Habib et al. ⁸⁹ Plisky et al. ⁹⁰
Full text unavailable (n = 3)	Franjoine et al. ⁹¹ Hanline et al. ⁹² Knuckles et al. ⁹³
Unrelated to postural control assessment (n = 4)	Barlaam et al. ⁹⁴ Flaters et al. ⁹⁵ Kim et al. ⁹⁶ Sprigle et al. ⁹⁷
Review article (n = 3)	Dietz et al. ⁸¹ Gan et al. ⁹⁸ Panisson et al. ³⁶
Normative study (reliability not discussed) (n = 3)	Chow et al. ⁹⁹ Foudriat et al. ¹⁰⁰ Tiwari et al. ¹⁰⁰
Results not reported separately for typically developing children (n = 1)	Lekskulchai et al. ¹⁰¹
Quoted unpublished data (n = 1)	Franjoine et al. ⁹¹

Appendix II B: Assessment of reporting quality of the studies using STROBE

No.	Author	STROBE item																							
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	Total Score	
1	Alsalaheen et al. ²¹	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	21	
2	Alsalaheen et al. ²⁴	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	22	
3	Alsalaheen et al. ³⁰	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	22	
4	Baker et al. ³³	1	1	1	1	0	1	1	1	1	0	1	1	1	1	1	1	1	1	0	1	1	0	18	
5	Barozzi et al. ²⁷	1	1	1	0	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	20	
6	Calatayud et al. ³⁹	1	1	1	1	0	1	1	1	1	0	1	1	1	1	1	1	1	1	0	1	1	0	18	
7	DeKegel et al. ²⁹	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	0	1	1	1	20	
8	Dewar et al. ⁴³	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	21	
9	Donahoe et al. ³⁷	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	0	1	1	0	19	
10	Emery et al. ³¹	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	0	20	
11	Geldhof et al. ²⁸	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	0	20	
12	Held et al. ⁴¹	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	0	1	1	1	1	20	
13	Holm et al. ⁴⁵	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	20	
14	Hunt et al. ²²	1	1	1	1	0	1	1	1	0	0	1	1	1	1	1	0	1	1	1	1	1	1	18	
15	Junge et al. ³⁴	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	21	
16	Khanna et al. ²⁵	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	0	1	1	1	1	1	1	20	
17	Leurer et al. ³⁵	1	1	1	1	1	1	1	1	1	0	1	1	0	1	1	1	1	1	1	1	1	0	19	
18	McLeod et al. ²³	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	0	1	1	0	19	
19	McLeod et al. ²⁶	1	1	1	1	1	1	1	1	1	0	1	1	0	1	1	1	1	1	1	1	1	0	19	
20	Panisson et al. ³⁶	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	0	1	1	1	20	
21	Rousson et al. ³²	0	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	0	1	1	1	19	
22	Shaikh et al. ⁴⁰	1	0	1	1	0	1	0	0	1	0	1	1	0	0	1	1	1	1	0	0	1	1	13	
23	Vilnai et al. ⁴⁴	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	0	20	
24	Volkmann et al. ³⁸	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	0	20	
25	Zaino et al. ⁴²	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	21	
	Total	24	24	25	24	21	25	24	24	23	4	25	25	22	24	25	23	25	24	16	24	25	15		

Appendix II C: Methodological quality assessment of studies (QAREL)

S.No.	Author	QAREL item											Total
		1	2	3	4	5	6	7	8	9	10	11	
1	Alsalaheen et al. ²¹	0	1	1	1	1	1	1	1	1	1	1	10
2	Alsalaheen et al. ²⁴	1	1	1	1	1	1	1	0	1	1	1	10
3	Alsalaheen et al. ³⁰	1	1	1	1	1	1	1	0	1	1	1	10
4	Baker et al. ³³	0	1	1	1	1	1	1	1	1	1	1	10
5	Barozzi et al. ²⁷	0	1	1	1	1	1	1	1	1	1	1	10
6	Calatayud et al. ³⁹	0	1	1	1	1	1	1	0	1	1	1	9
7	DeKegel et al. ²⁹	0	1	1	1	1	1	1	1	1	1	1	10
8	Dewar et al. ⁴³	0	1	1	1	1	1	1	1	1	1	1	10
9	Donahoe et al. ³⁷	0	1	1	1	1	1	1	1	1	1	1	10
10	Emery et al. ³¹	0	1	1	1	1	1	1	1	1	1	1	10
11	Geldhof et al. ²⁸	0	1	1	1	1	1	1	0	1	1	1	9
12	Held et al. ⁴¹	1	1	1	1	1	1	1	1	1	1	1	11
13	Holm et al. ⁴⁵	0	1	1	1	1	1	1	0	1	1	1	9
14	Hunt et al. ²²	0	1	1	1	1	1	1	0	0	1	1	8
15	Junge et al. ³⁴	0	1	1	1	1	1	1	1	1	1	1	10
16	Khanna et al. ²⁵	0	1	1	1	1	1	1	1	1	1	1	10
17	Leurer et al. ³⁵	1	1	1	1	1	1	1	0	1	1	1	10
18	McLeod et al. ²³	1	1	1	1	1	1	1	1	1	1	0	10
19	McLeod et al. ²⁶	0	1	1	1	1	1	1	1	1	1	1	10
20	Panisson et al. ³⁶	1	1	1	1	1	1	1	0	1	1	1	10
21	Rousson et al. ³²	0	1	1	1	1	1	1	0	1	0	1	8
22	Shaikh et al. ⁴⁰	0	1	1	1	1	1	1	0	0	1	1	8
23	Vilnai et al. ⁴⁴	0	1	1	1	1	1	1	1	1	1	1	10
24	Volkman et al. ³⁸	1	1	1	1	1	1	1	1	0	1	1	10
25	Zaino et al. ⁴²	0	1	1	1	1	1	1	1	1	1	1	10
	Total	7	25	25	25	25	25	25	15	22	24	24	

CHAPTER III

Characterization of Cervical Spine Impairments in Children and Adolescents Post-Concussion

Abstract

Background. Patients with concussion may present with cervical spine impairments, therefore accurate characterization of cervical post-concussion impairments is needed to develop targeted physical therapy interventions.

Purpose. To characterize the type, frequency and severity of cervical impairments in children and adolescents referred for physical therapy after concussion.

Study design. Retrospective study

Methods. A retrospective analysis was conducted for 73 consecutive children and adolescents who received cervical physical therapy following a concussion. Data was classified into six broad categories. The frequency and intensity of cervical impairments within and across the categories was reported.

Results. Ninety percent of patients demonstrated impairments in at least 3 out of 5 categories whereas 55% demonstrated impairments in at least 4 out of 5 categories. Out of five impairment categories, posture (99%) and myofascial impairment (98%) demonstrated highest impairment frequency followed by joint mobility (86%) and muscle strength (62%). Cervical joint proprioception was the least evaluated impairment category.

Conclusion. High prevalence of cervical spine impairments was observed in this study with muscle tension, joint mobility and muscle strength being most commonly impaired. The categories of impairments examined in this cohort were consistent with the recommendations of the most recent clinical practice guidelines for neck pain. This study provides preliminary data to support the framework of a cervical spine evaluation tool in children and adolescents following

concussion. Future studies should aim to develop screening tools to evaluate possible cervical spine impairments in patients with concussion.

Clinical relevance. Evidence suggests involvement of cervical spine in youth who sustain a concussion. However, the extent and characterization of cervical spine involvement is yet to be established, especially in children and adolescent with concussions.

Key words. Traumatic brain injury, youth, cervicogenic, movement system

Introduction

Concussion is defined as a complex pathophysiological process affecting the brain which is induced by biomechanical forces.¹ Concussion is one of the most common athletic injuries in the United States and is a growing concern among children and young adults. In any given year, 43,200 to 67,200 of the 1.2 million total high school football players in the U.S. sustain concussions, with adolescents 15-19 years being most susceptible.²⁻⁴ Of the 502,000 children and adolescents diagnosed with concussion between years 2001 and 2005, 35% were estimated to fall between the ages of 8-13 years.⁵ Prevalence of post-concussion symptoms has been reported in previous studies with 90-92.2% of athletes experiencing headaches, 90% experiencing neck pain, and 68.9% experiencing dizziness.⁶⁻⁸

Cervical musculoskeletal attributes such as neck strength may represent a modifiable risk factor for concussion^{9,10} and biomechanical similarities exist between concussion and whiplash injuries. Previous researchers have suggested a need for a structured cervical spine examination following a concussion.^{11,12,13} This recommendation is further supported by the overlap between concussion symptoms and whiplash injuries.^{1,12-14} The transmission of forces to the head during a concussion may result in trauma to the cervical spine.^{1,15} Axial loading, hyperflexion and hyperextension of cervical spine are the most frequently reported mechanisms of injury to the cervical spine associated with various sports such as football, hockey and wrestling.^{1,15}

Previous studies indicated that children demonstrated less cervical strength and greater head to body ratio than adults.¹⁶⁻¹⁸ Therefore, children may not be able to generate sufficient tensile stiffness to control the head's response to impulsive loads,¹⁹ and may experience greater head acceleration compared to adults.²⁰ Moreover, it has been postulated that children exhibit reduced ability to efficiently dissipate energy from a head impact primarily due to

underdevelopment of the neck and shoulder musculature.¹¹ Smaller and weaker cervical muscle attributes in children may predispose them to greater cervical impairments after a concussive event, and warrant a thorough characterization of cervical post-concussion impairments in adolescents.

Prior authors have acknowledged that patients may often experience post-concussion symptoms pertinent to the cervical spine.²¹⁻²⁴ Signs and symptoms such as decreased range of motion, muscle tenderness, headaches, stiffness and radicular symptoms have been reported to occur post-concussion.²² Studies have documented that more than 50% of patients continue to demonstrate symptoms such as headache, fatigue and dizziness even after the expected recovery timeframe post-concussion.^{23,25}

A comprehensive multifaceted approach to evaluation and treatment of post-concussion impairments must acknowledge heterogeneity of impairments including central and autonomic nervous system impairments, cervical and thoracic spine impairments, and vestibular and oculomotor impairments. A variable combination of impairments across these categories will contribute to the overall constellation of symptom.^{12,23,26} For the best possible outcomes, physical therapy interventions must be based on specific impairments that are found during evaluation.²³ Impairment-directed therapeutic interventions would result in supporting progression to subsequent clinical trials to establish efficacy and enhance practice patterns.^{23,27}

Despite the consensus that a thorough cervical examination is needed in patients with concussion,^{12,28} the evidence for accurate characterization of common cervical impairments after concussion in children and adolescents (i.e. ≤ 18 y) is sparse.^{29,30} Although the most recent Clinical Practice Guidelines (CPG) for neck pain thoroughly reviewed the literature surrounding neck pain and associated cervical impairments, studies including children (i.e. <18 years) were

excluded from the CPG.³¹ Moreover, authors of the CPG recommend further research into treatment of patients with neck pain because of a concussion.³¹ Accurate characterization of the type, number and severity of cervical post-concussion impairments is needed for accurate identification of targeted interventions.^{12,21} Hence, this study was conducted to characterize the type, frequency and severity of cervical impairments after concussion. This study will provide valuable insights into the extent and nature of cervical spine impairments post-concussion that may provide a foundation to develop targeted physical therapy interventions.

Methods

Setting

The data for this study was collected from the electronic medical records of a tertiary center specializing in comprehensive interdisciplinary management of for patients with concussion. The study was approved by the Institutional Review Board of the primary investigator's institution.

Design and participants

A retrospective chart review was conducted for 73 children and adolescents between the ages of 8 to 18 years who received cervical physical therapy following a concussion from January 1, 2017 to August 31, 2017. The patients were referred from emergency and athletic departments to the tertiary clinic by care providers. In the clinic, a physician performed symptom-based examination that included a brief cervical spine screening in patients endorsing neck pain at the time of their visit. A brief cervical screening included tests for ligamentous stability, followed by range of motion testing, palpation, or segmental mobility testing. Following examination, the patients were referred to cervical physical therapy if indicated. Seven physical therapists performed examination on patients, and recorded their findings. Upon inception of the concussion management program in this tertiary clinic, all seven treating therapists were trained to standardize administration of the tests and used standardized assessment forms as a measure of quality assurance. Demographic and clinical information was retrieved from electronic medical records.

Procedures

A data extraction sheet was developed by two investigators (DT and BA). The investigators independently extracted data for 5 random patients and the extracted data was compared to ensure consistency in data extraction. After ensuring quality of the extracted data, the primary investigator (DT) completed the remaining data collection.

Assessment data from the first physical therapy visit was extracted. In the event that a full assessment was not completed due to excessive increase in patient's symptoms, the subsequent two visits were screened to extract additional assessment data.

Outcome Measures

Demographic, injury and care process data. Demographic and injury characteristics were retrieved from electronic medical records. These characteristics included age, gender, primary sport(s), prior history of migraine or prior learning disabilities, date of sustaining concussion and mechanism of injury. In addition, the date of first medical visit, date of first physical therapy visit, total number of physician visits and total number of physical therapy visits were also collected.

Self-reported symptoms and cervical symptoms disability. Sports Concussion Assessment Tool 3rd edition (SCAT-III) symptom evaluation checklist: SCAT-III is a concussion evaluation tool that was developed from the original SCAT to make decisions regarding return to play.³² This study utilized the symptom evaluation checklist of the SCAT_III. The data on symptom severity score was collected on 22 concussion related symptoms including cognitive,

physical, sleep and affect related symptoms using a Likert scale (0 = none, 6 = severe), where higher scores indicated greater symptom severity (maximum possible score = 132).²⁸

Neck disability index (NDI). The NDI is a self-reported measure with 10 items that is used to record perceived disability in patients with neck pain.³³ The NDI scores were interpreted as described by Vernon and Mior³⁴ where score of 0-4 indicated no disability, 5-14 mild disability, 15-24 moderate disability, 25-34 severe disability and scores above 35 indicated complete disability with a maximum possible score of 50.^{34,35} The NDI demonstrated moderate test-retest reliability (intraclass correlation coefficient (ICC) = 0.5, CI = 0.25-0.67), fair to good construct validity with neck pain numeric rating scale scores ($r = 0.3-0.7$); and adequate responsiveness with global rating of change scale as an anchor for distinguishing improved vs stable patients with neck pain (Area under the curve (AUC)= 0.75-0.9).³⁶

Screening for ligamentous instability. Data on special tests for upper cervical ligamentous instability including tests for alar ligament and transverse ligament was collected.³⁷

Test for alar ligament.: The test for alar ligament was performed with patient in a seated position.³⁸ The examiner's palm was placed on the forehead and index finger of the other hand was placed on the tip of spinous process of second cervical vertebra. The examiner then side bends and rotates the patient's head to the left or right while stabilizing C2. The test is considered positive for instability if movement between head and neck is observed.^{37,38} This test demonstrates high specificity (0.88-1) and moderate to high sensitivity (0.54-0.84) to detect ligamentous instability in patients with whiplash disorder.^{39,40}

Test for transverse ligament. The test for transverse ligament was performed with the patient in supine position with examiner supporting the head. Examiner's index finger was

placed between the occiput and spinous process of C2 vertebra. The head and C1 vertebra was then lifted anteriorly, not allowing either flexion or extension and the position was maintained for approximately 15 seconds. The test was considered positive if the patient exhibited nausea/vomiting, reported lip paresthesia, lump in the throat sensation, dizziness, headache or muscle spasm.⁴¹ This test demonstrates high specificity (0.96-1) and moderate to high sensitivity (0.51-0.79) for patients with whiplash disorder.^{39,40}

Cervical Physical Therapy Examination. Cervical physical therapy assessment data was classified into six broad assessment categories. These assessment categories included posture, movement quality and generalized joint hypermobility (GJH), myofascial tension to palpation, joint mobility, muscle strength and endurance, proprioception, special tests for upper extremity radicular symptoms.

Insert Figure 1 about here

Posture, movement quality, Generalized Joint Hypermobility (GJH). Posture: Forward head posture, scapular winging and increase in thoracic kyphosis were the dysfunctions assessed by observation using an ordinal scale (no/mild/moderate/severe). Posture was classified as impaired if a patient has one or more of these dysfunctions. As a part of continuous quality assurance initiative in our clinic, the treating therapists underwent a training to standardize the evaluation procedure and to ensure inter-rater reliability using standardized patients. For assessment of posture, treating therapists demonstrated high reliability as indicated by 100% percent agreement in their assessment of cervical postural abnormalities.

- **Scapulo-humeral rhythm.** Scapulo-humeral rhythm is defined as the ratio of glenohumeral movement to scapulothoracic movement during arm elevation.⁴² Scapulo-

humeral rhythm was assessed by observation using an ordinal scale of good (symmetric, full motion), fair (symmetric, not full motion) and poor (asymmetric, not full motion). In this study, scapulo-humeral rhythm was considered abnormal if it was rated as fair or poor.

- **Beighton test.** Greater than normal joint laxity across joints has been associated with a range of connective tissue disorders. Evidence suggests that children with Generalized Joint Hypermobility (GJH) experience greater pain as compared to those without hypermobility. Morris and colleagues reported that adolescents with GJH had higher odds of musculoskeletal pain after participating in sports as compared to children who did not have GJH (Odds ratio = 2.51 (1.48-4.26)).⁴³ Also, GJH has been reported to contribute to chronic pain, fatigue and impaired proprioception in children thereby limiting their activity and participation.⁴⁴ Beighton test is a measure to evaluate GJH in children.⁴⁵ The test items include passive dorsiflexion of 5th metacarpophalangeal joint, passive elbow hyperextension, passive knee hyperextension (all three bilaterally measured by goniometry), bilateral passive opposition of the thumb to the flexor side of forearm and forward flexion of the trunk with knees straight.^{45,46} It is scored on a 0-9 scale where a score of 5 or greater indicates GJH.^{37,47}

Test results were interpreted as presence (a score of ≥ 5) or absence (a score of < 5) of GJH. Beighton test demonstrates good intra-rater (ICC = 0.96-0.98) and fair inter-rater (ICC = 0.73) reliability and has been documented as a valid measure to assess GJH in healthy children and adolescents.^{46,47}

Myofascial tension to palpation.

- **Tension to palpation.** For this study, muscle tension to palpation was defined as a persistent painful contraction that could not be completely relaxed by voluntary effort.⁴⁸ Data on myofascial tension to palpation (no, mild, moderate, severe) for specific cervical muscle groups and individual muscles (paraspinals, suboccipitals, upper trapezius, levator scapulae, sternocleidomastoid and scalenes) was collected for both right and left sides. Presence or absence of tension to palpation was assessed on a 0-3 Likert scale (0 = No tension, 3 = severe tension). If tension was present, then the data was further categorized as unilateral or bilateral presence of tension to palpation for each muscle group. Palpation of muscle has previously been shown to demonstrate discriminant validity, high specificity (> 0.90) and acceptable reliability ($ICC = 0.59 - 0.93$).^{49,50} Additionally, our pilot data indicate that treating therapists demonstrated good agreement between their scoring of palpation tests. (Percent agreement = 83.33%).

Joint mobility. Joint mobility was further categorized in to range of motion (ROM) and pain, and segmental mobility testing.

- **Range of motion (ROM) and pain:** Data on active range of motion for cervical spine for flexion, extension, side bending and rotation (right and left) were recorded using cervical range of motion assessment device (CROM). Data was classified using previously published percentile values.⁵¹ Consistent with previous studies that used a median split to define high and low performers, scores less than the median (i.e. $< 50^{\text{th}}$ percentile) in each direction were considered abnormal.^{51,52} The frequency of abnormalities was reported for each direction. Additionally, the total number of abnormal

directions was reported for each patient. Neck pain associated with cervical spine movements was recorded as presence or absence of pain (yes/no) with movement. The frequency of pain was reported for each movement, and the total number of painful directions was reported for each patient.

- **Segmental mobility testing.** Segmental mobility of the cervical spine was assessed in prone position using posterior to anterior glide.^{53,54} Each segment was classified as hypomobile, hypermobile, or normal). The data for cervical spine was further classified according for the upper cervical (C0- C2) and the lower cervical spine (C3-C7). Based on these scores, the overall mobility was rated as hypomobile (hypomobile for one or more segments), normal (normal for all segments), or hypermobile (hypermobile for one or more segments).⁵⁵ Patients that presented with hypermobility in some segments but hypomobility in others were reported as mixed findings. Previous studies have reported variable reliability for segmental mobility tests.⁵⁶⁻⁵⁸ To ensure consistency, we calculated reliability among treating therapists and found acceptable reliability for segmental mobility tests (percent agreement = 66-100%).

Muscle strength and endurance. This category included manual muscle testing, neck flexor endurance and cranio-cervical flexor test.

- **Manual Muscle Test (MMT).** This consisted of manual muscle testing of upper, middle and lower trapezius, rhomboids and cervical flexors (i.e. Longus Colli and Sternocleidomastoid) on a 0-5-point scale (0 = no perceptible muscle contraction & 5 = muscle holds test position against “full pressure”).^{59,60} The data was classified as normal (5/5) or abnormal strength (<5/5). Muscle strength was considered impaired if deficits were observed on MMT.⁶⁰

- **Neck flexor endurance test (NFET).** NFET is a timed test that is used to evaluate muscle endurance of cervical flexors. In this test, the patient maintained a chin tuck position in supine lying while holding the head 2.5 cm above the supporting surface.^{61,62} The test was considered normal if the patient was able to maintain the required position for 38 seconds or more.⁶³ The NFET demonstrates moderate to good intra-rater (ICC = 0.67-0.93) and inter-rater (ICC = 0.69-0.96) reliability.^{61,64}
- **Cranio-cervical flexor test (CCFT).** The test consisted of five, 2-mm Hg progressive pressure increases from a baseline of 20-mm Hg to a maximum of 30-mm Hg. The patient was required to maintain isometric contraction for more than 10 seconds at each pressure level without substituting with superficial neck muscles.⁶⁵ The CCFT is a reliable test (ICC = 0.98-0.99) used to assess progressive activation and endurance of deep cervical flexors.⁶⁵

Proprioceptive testing.

- **Joint position error test (JPET).** This test measures the neck reposition sense reflecting afferent input from the neck joint and muscle receptors. The test was performed with patient in a seated position. The examiner established the neutral head position by focusing a laser pointer on the target. The patient received visual feedback for the neutral head position. The patient then performed active head rotation on one side with eyes closed and attempted to return to neutral head position. Final position of the laser point indicated error related to the center of the target.⁶⁶

The test was performed for right and left rotation. An error of more than 4.5 degrees or 7 centimeters was considered as clinically significant.⁶⁷ The test was considered normal if the

patient could return to the neutral head position with an error < 4.5 degrees or 7 cm in at least 2 out of 3 trials. The JPET demonstrates fair to excellent reliability ($ICC = 0.35-0.9$) in evaluating cervico-cephalic kinesthesia.⁶⁸

Special tests for upper extremity radicular symptoms

Spurling test: Spurling test was used to evaluate radicular symptoms. The patient performed lateral flexion and extension of the cervical spine. This was followed by application of axial pressure on the spine by the examiner. The test was considered positive if symptoms such as pain or tingling were reproduced.⁶⁹ Spurling test demonstrates acceptable reliability ($Kappa = 0.60 (0.25-0.99)$)⁷⁰ and diagnostic accuracy (sensitivity = 52.9%, specificity = 93.8%) to evaluate radicular symptoms.⁷¹

Statistical Analysis

The demographic, injury and process of care data were expressed using descriptive statistics. All calculations were performed using Statistical Package for Social Sciences (SPSS) version 24.0 (SPSS Inc., Armonk, NY).

The frequency of patients with a specific impairment as well as the number of impairments exhibited by each patient was presented using descriptive statistics i.e. frequency and percentages.

Spinal and rib mobility impairments, muscle strength and muscle guarding impairments were described as frequencies and percentages. Active range of motion were expressed as percentiles compared to normative data.^{51,52} Joint position error test was reported as normal or abnormal whereas Beighton test was reported according to the presence or absence of GJH.

The distribution of myofascial tension, cervical and thoracic segmental mobility, and results on Spurling test were reported as percentages.

Results

Demographics, mechanism of injury and process of care

Data for 73 patients was collected in this study. The average age of patients was 14.6 ± 2.5 years (44% males). Thirty percent of patients sustained concussion after contacting the playing surface, 21% of the injuries were resulted from contact with another player whereas 18% of patients sustained injury from coming into contact with sporting equipment. Mechanism of injury was not sport-related for 29% of patients. Data on injury mechanism was not available for 3% of patients ([Table III.1](#)).

Thirty-eight percent of patients had a history of migraine; more specifically, 51% of female patients (21/41) and 22% of male patients (7/32) had a history of migraine, 14% had attention deficit, 12% had a known learning disability, and 10% of patients had attention deficit hyperactivity disorder.

The median time to first physician visit following injury was 16 days and the median time taken for physical therapy evaluation following their first physician visit was 6 days ([Table III.1](#)).

Self-reported symptom, cervical symptom disability, and screening for ligamentous instability

The average score on SCAT-III was 34 with scores ranging from 0- to 119) out of a possible score of 132. Patients reported an average of 14 individual symptoms (Range: 0-22) symptoms at initial physician visit. On NDI, 70% of patients reported disability attributed to neck pain (29% mild, 32% moderate, 8% severe and 1% complete) whereas only 15% of patients

reported no disability. The NDI was not tested in 15% of the patients. All patients demonstrated intact cervical ligamentous integrity as indicated by negative findings on the tests for the alar and the transverse ligaments.

Cervical physical therapy assessments

Posture (99%) and myofascial impairment (98%) demonstrated highest impairment frequency. Joint mobility was impaired in 86% of patients and muscle strength were impaired in 62% of patients ([Table III.2](#)). Cervical joint proprioception was quantified only 29% of participants. Because proprioception was not examined in 71% of patients, it was not included in the aggregated results quantifying the frequency of patients exhibiting impairments across the remaining five categories. Of the remaining five impairment categories, 90% of patients demonstrated impairments in at least 3 out of 5 categories whereas 55% demonstrated impairments in at least 4 out of 5 categories.

Posture, movement quality, and GJH

Posture abnormality was the most common impairment observed in this study. Forward head posture was observed in 99% of patients, 86% of patients demonstrated increased thoracic kyphosis, and scapular winging was observed in 74% of patients ([Table III.3](#)). Forty-eight percent of patients demonstrated abnormal scapulo-humeral rhythm ([Table III.3](#)). GJH was the least common impairment as only 14% of patients demonstrated hypermobility as indicated by the findings of Beighton test ([Table III.3](#)).

Myofascial tension to palpation

Data on myofascial assessment revealed that 98% of patients demonstrated increased muscle tension. Upper trapezius (86%) and suboccipitals (83%) demonstrated highest percentage of patients with bilateral muscle tension followed by paraspinals, scalenes, levator scapulae and sternocleidomastoid (70-79%) ([Table III.4](#)).

Joint mobility

Cervical spine extension was found to be the most limited (i.e. <50 percentile) movement (77%) followed by side bending (L = 55; R = 59%), flexion (45%) and finally rotation (L = 41; R = 42%). Overall, 90% of patients demonstrated impaired cervical AROM in one or more direction of movement (6 directions = 15%, 5 directions = 12%, 4 directions = 18%, 3 directions = 19 %, 2 directions = 12 %, 1 direction = 14%). Percentile scores for all AROM movements are reported in [Table III.5](#).

Twenty-three percent of patients reported neck pain with cervical flexion, closely followed by extension (22%) whereas up to 18 % of patients reported pain with side bending or rotation ([Table III.5](#)). Twelve percent of patients demonstrated pain with movement in one direction, 11% demonstrated pain with movement in two directions whereas 17% demonstrated pain in more than 2 directions of movement. Fifty-six percent of patients demonstrated no pain with cervical spine movements.

Seventy-one percent of patients demonstrated hypomobility exclusively in upper cervical spine segments (C0- C2), 52% demonstrated hypomobility in more than two spinal segments and 4 % demonstrated hypomobility only in lower cervical spine segments (C3-C7). In terms of thoracic mobility, T1-T4 segments were most commonly evaluated and demonstrated

hypomobility in 60% of patients. Similarly, first rib was most commonly evaluated and 41% of patients demonstrated hypomobility ([Table III.6](#)).

Muscle strength and endurance

Manual muscle testing data revealed that rhomboids were the most common muscles to demonstrate weakness i.e. muscle strength < grade 5 (35%) followed closely by middle (30%) and lower trapezius (31%) whereas upper trapezius was found to be the muscle group that demonstrated weakness in least number of patients (3%) ([Table III.7](#)). The neck flexor endurance was abnormal in 40% of patients indicating poor endurance ([Table III.7](#)). Since CCFT was the least common of the strength measures used (performed in only 4% of patients), the data was not considered adequate to draw meaningful inferences and hence not reported.

Upper extremity radicular symptoms

None of the patients demonstrated upper extremity radicular symptoms on Spurling test.

Discussion

High prevalence of cervical spine impairments was observed in this study with over 90% of patients demonstrating impairments in 3 or more categories. Most commonly observed impairments were noted in muscle tension, joint mobility and muscle strength. The categories of impairments examined in this cohort are consistent with the impairments reported in the most recent clinical practice guidelines for neck pain.³¹

Cervical spine injuries may independently contribute to many concussion symptoms including headaches, dizziness, neck pain, disturbance of concentration or memory, irritability, sleep disturbance, and fatigue.¹³ The findings of our study revealed that over 70% of the patients had upper cervical spine mobility impairments. Similar findings were noted in a recent preliminary report that observed range of motion and segmental mobility impairments primarily affecting the upper cervical spine.²⁹ Upper cervical spine (C1- C3) has previously been reported to contribute to most of the cervicogenic symptoms observed following trauma including cervicogenic headaches, dizziness and unsteadiness.^{13,14,72} Factors including cervical zygapophyseal joint mobility impairments and abnormal somatosensory inputs from upper cervical and trigeminal sensory afferents may explain headaches and dizziness following cervical spine injury.¹²⁻¹⁴ High occurrence of headaches (84%) and dizziness (57%) among the patients in this study warrants detailed examination of upper cervical spine mobility in this population.

High pain intensity and high NDI scores have been identified as risk factors for having persistent symptoms if present after acute whiplash.³¹ Pain associated with cervical spine movement could be attributed to altered axio-skeletal muscle activity and dysfunction in scapular mobility as reported by Helgadottir and colleagues⁷³ in young adults with whiplash injury.⁷³

Moderate to high level evidence exists for evaluation of neck pain intensity and collecting NDI scores to establish prognosis following whiplash.³¹ In this study, 40% of patients demonstrated moderate to severe disability on NDI thereby indicating the lasting perception of disability following concussion. However, it is important to note that NDI has not been validated in individuals younger than 18 years of age and may not capture the true extent of cervical disability perceived by adolescents.

Daenen and colleagues⁷⁴ reported that alterations in muscle activity continue to exist over time following whiplash trauma, indicating the need of strength and endurance evaluation for treatment and prevention of re-injury.^{61,74} In this sample, muscle strength and endurance deficits were observed among 40% of the patients.

Although the clinical practice guidelines on neck pain recommended the use of cranial-cervical flexion and neck flexor muscle endurance test in patients with all types of neck pain and movement-coordination impairments,³¹ these tests were not frequently performed by the treating therapists. CCFT and NFET were not tested due to the acute nature of the injury, increased pain level and increased muscle guarding upon testing.

Out of the patients that were tested for JPET (n = 21) in this study, 14 were found to have impaired position sense. The control of head position has been reported to be affected when neck proprioceptive information is inaccurate, which has been observed in patients with chronic non-traumatic neck pain as well as with whiplash-type injuries.^{12,75} Impairments in position sense may contribute to dizziness, disequilibrium and impaired postural control.⁷⁵ The high percentage (66%) of abnormal joint position sense in those participants that were tested may warrant consideration for including this test in evaluation of this population. However, completion of

JPET in the first visit may have not been feasible, especially in patients with other various documented impairments.

Additionally, active range of motion at the cervical spine has been associated with both proprioception and oculomotor performance in adults with whiplash-type injuries, thereby indicating a role of zygapophyseal joints in proprioceptive dysfunction.⁷⁶ Increased muscle tension of the cervical spine musculature, may also result in impaired proprioceptive signals.⁷⁶ This close association of cervical proprioceptive inputs to the contribution of head position and equilibrium reinforces the need for detection of cervical joint position error to determine the source of balance problems and initiate appropriate intervention strategies (cervical or vestibular).

Previous literature has indicated that children and adolescents have lesser mobility as compared to young adults.^{77,78} Similar findings were observed in this study with over 70% of participants demonstrating hypomobility. However, the lack of a perfect relationship between range of motion deficit and the results of segmental mobility testing can be explained by various reasons. First, many patients presented with hypomobility in some segments and hypermobility in others, which may have not affected the ROM results. Cervical spine segments adjacent to hypomobile segments may become hypermobile, creating an unimpaired active range of motion.⁷⁸ Second, range of motion can be influenced by factors other than segmental mobility. These factors can include pain, altered posture, and limited cervical muscle extensibility and motor control deficits.^{79,80}

It was also noteworthy that none of the patients tested positive for alar or transverse ligament instability and/or radicular symptoms during physical therapy evaluation in this study.

Tests for ligamentous integrity have been reported to have sufficient specificity but demonstrate high variability in sensitivity, and therefore need to be interpreted with caution.⁴⁰

Limitations. Several limitations were associated with this study. Many of the tests employed in this study are subjective and may not demonstrate ideal reliability. Although the therapists underwent training to standardize administration of tests for quality assurance and to improve inter-rater reliability, it is possible that the inherently subjective nature of these tests influenced the findings of this study. Variations in the choice of tests and in grading and interpretation of the tests administered at initial evaluation could have influenced the prevalence of impairments found in this study. Additionally, pain associated with segmental mobility could not be documented in this study due to inconsistencies with documentation. Since reproduction of symptoms is important for localizing impaired segments,^{57,58} future studies should focus on pain assessment with segmental mobility.

The cervical physical therapy examination was impairment-guided and was often dictated by injury acuity and patient's tolerance to testing. Since patients varied in injury acuity, tolerance to assessment, and in exhibited impairments, not all tests were conducted on all patients. This may have biased the reported prevalence of the impairments by over-representing impairments on tests that were administered more often and under-representing the prevalence of impairments identified in tests that were done less often. Additionally, assessment of radiculopathy using only the Spurling test instead of utilizing the Wainner's test item cluster⁷⁰ may have led to underrepresentation of the prevalence of radiculopathy in the sample. In this study, we reported the percentage of patients in which a particular test was not administered. Therefore, clinicians are encouraged to take that in consideration when interpreting the prevalence of cervical impairments reported in this study.

Given the cross-sectional design of this study, it is unclear if exhibited cervical impairments (i.e. limited ROM, limited segmental mobility, increased muscle tension and altered posture) were present before concussion or if they were attributed to concussion. Although it is possible that cervical impairments exist in non-concussed children,⁸¹⁻⁸³ its presence in post-concussion children may contribute to post concussion symptoms. Therefore, although a cause and effect relationship cannot be ascertained between cervical impairments and concussion, targeted assessment and rehabilitation of cervical impairments after concussion is warranted.^{21,22,26}

Impairments identified in this study are subjected to sample bias and may not represent the prevalence of cervical impairments in the wide spectrum of concussion patients. Nonetheless, given the clear link between common concussion symptoms and cervical impairments^{7,12}, findings of this study can provide a foundation for clinicians aiming to identify cervical impairments in patients with concussion.

Conclusion

This study has attempted to characterize specific cervical spine impairments in patients referred for physical therapy after concussion. The findings of this study provide preliminary data to support the framework of a cervical spine evaluation tool in children and adolescents following concussion. Future studies should aim to develop screening tools to evaluate possible cervical spine impairments in patients with concussion and to refer for a thorough cervical spine evaluation if cervical spine impairments are suspected.

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Figure 1: Assessment categories

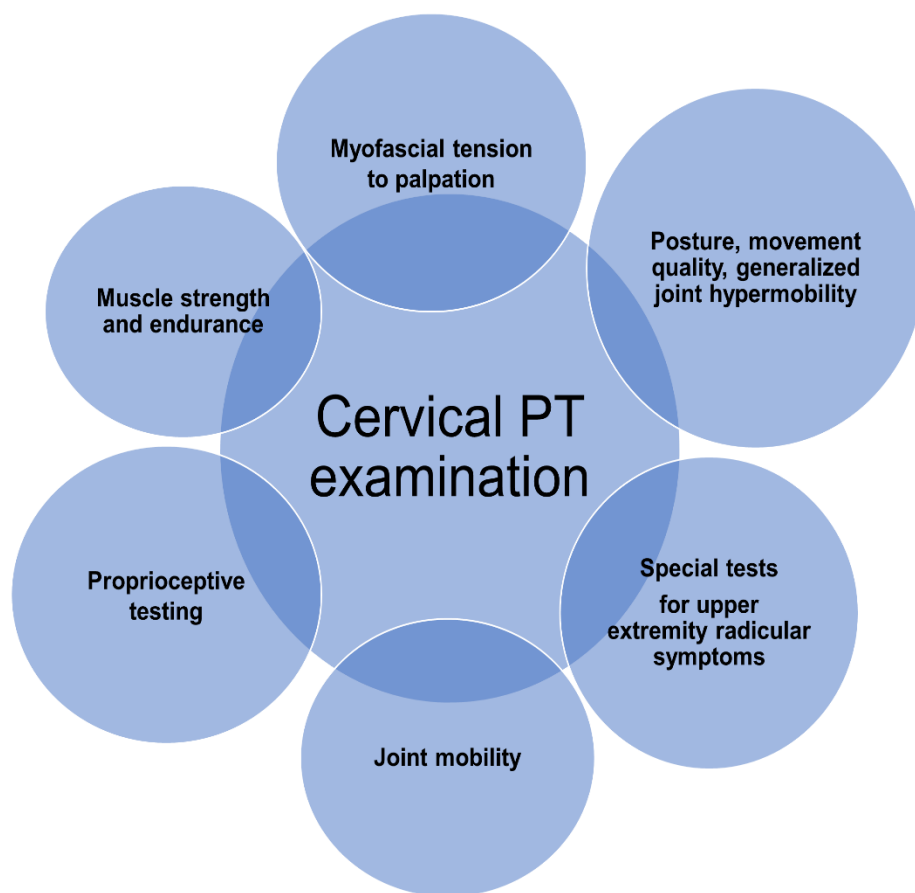


Table III.1. Demographic, injury and care characteristics of participants

N (% males)	73 (44)
Age in years, mean (SD)	14.6 (2.5)
Attention deficit, n (%)	10 (14)
Attention deficit hyperactivity disorder, n (%)	7 (10)
Learning disability, n (%)	9 (12)
History of migraine, n (%)	28 (38)
Mechanism of injury N (%)	
Contact with another player	15 (21)
Contact with playing surface	22 (30)
Contact with sporting equipment	13 (18)
Others (Non-sport related)	21 (29)
Not specified	2 (3)
Process of care, Median (Min – Max)	
Days to first physician visit following concussion	16 (1-237)
Days to first PT visit following physician visit	6 (0-380)
Number of physician visits	4 (1-11)
Number of physical therapy visits	3 (1-14)

Table III.2. Frequency of patients exhibiting with impairments in the six assessment categories

Impairment	N (%)		
	Abnormal	Normal	Not tested
Posture, movement quality & generalized joint hypermobility	72 (99)	0 (0)	1 (1)
Joint mobility	63 (86)	6 (8)	4 (6)
Myofascial tension to palpation	71 (98)	1 (1)	1 (1)
Muscle strength and endurance	45 (62)	8 (11)	20 (27)
Proprioception	14 (19)	7 (10)	52 (71)
Special tests for upper extremity radicular symptoms	0 (0)	71 (97)	2 (3)

Table III. 3. Impairment frequencies in posture, movement quality & generalized joint hypermobility

Test	N (%)				
Posture					
	Mild	Moderate	Severe	Absent	Not tested
Forward head	29 (40)	37 (51)	6 (8)	0 (0)	1 (1)
Scapular winging	34 (47)	20 (27)	0 (0)	6 (8)	13 (18)
Increased thoracic kyphosis	34 (47)	28 (38)	1 (1)	5 (7)	5 (7)
Scapulohumeral Rhythm	Abnormal		Normal		Not tested
	35 (48)		12 (16)		26 (36)
Beighton test	Hypermobile		Normal		Not tested
	10 (14)		23 (31)		40 (55)

Table III. 4. Myofascial tension to palpation (N=73)

Muscle groups	Bilateral TTP N (%)	Unilateral TTP N (%)	No tension TTP N (%)	Not tested N (%)
Paraspinals	57 (79)	4 (5)	8 (11)	4 (5)
Suboccipitals	60 (83)	3 (4)	6 (8)	4 (5)
Upper trapezius	63 (86)	2 (3)	5 (7)	3 (4)
Levator scapulae	52 (72)	3 (4)	12 (16)	6 (8)
Sternocleidomastoid	51 (70)	3 (4)	12 (16)	7 (10)
Scalene	53 (73)	4 (5)	13 (18)	3 (4)
Note: TTP = Tension to palpation				

Table III. 5. Percentile distribution for cervical active range of motion and pain with range of motion testing

N (%)															
Percentile	<2.5	2.5	5	10	20	30	40	50	60	70	80	90	95	97.5	Missing
Flexion	0 (0)	6 (8)	0 (0)	0 (0)	8 (11)	6 (8)	13 (18)	1 (1)	4 (6)	12 (16)	4 (6)	3 (4)	5 (7)	6 (8)	5 (7)
Extension	14 (19)	11 (15)	3 (4)	15 (21)	1 (1)	3 (4)	9 (12)	2 (3)	0 (0)	7 (10)	2 (3)	0 (0)	0 (0)	1 (1)	5 (7)
Left SB	10 (14)	3 (4)	5 (7)	16 (22)	3 (4)	0 (0)	3 (4)	1 (1)	2 (3)	12 (16)	6(8)	1 (1)	4 (6)	2 (3)	5 (7)
Right SB	12 (16)	6 (8)	4 (6)	2 (3)	17 (23)	2 (3)	0 (0)	2 (3)	1 (1)	12 (16)	5 (7)	1 (1)	3 (4)	1 (1)	5 (7)
Left Rot.	7 (10)	1 (1)	15 (21)	1 (1)	0 (0)	6 (8)	0 (0)	17 (23)	3 (4)	3 (4)	4 (6)	7 (10)	3 (4)	0 (0)	6 (8)
Right Rot.	8 (11)	2 (3)	2 (3)	13 (18)	1 (1)	5 (7)	0 (0)	2 (3)	18 (24)	3 (4)	2 (3)	8 (11)	0 (0)	3 (4)	6 (8)
Pain with movement															
				Yes				No				Not tested			
Flexion				17 (23)				53 (73)				3 (4)			
Extension				16 (22)				54 (74)				3 (4)			
Rotation (Right)				12 (16)				58 (80)				3 (4)			
Rotation (Left)				10 (14)				60 (82)				3 (4)			
Side bending (Right)				13 (18)				57 (78)				3 (4)			
Side bending (Left)				11 (15)				59 (81)				3 (4)			
Note: SB = Side bending, Rot. = Rotation															

Table III. 6. Segmental spine and rib mobility results

N (%)					
	Hypomobility	Hypermobility	Normal	Not tested	Mixed findings
All cervical segments	19 (26)	1 (1)	8 (11)	2 (3)	43 (59)
Upper cervical spine only (C0-C1 & C1-C2)	52 (71)	2 (3)	14 (19)	5 (7)	NA
Lower cervical spine only (C3-C7)	3 (4)	3 (4)	34 (47)	4 (5)	29 (40)
More than two spinal segments	38 (52)	3 (4)	NA	4 (5)	28 (39)
T1-T4	43 (60)	1 (1)	17 (23)	12 (16)	NA
T5-T8	15 (21)	1 (1)	16 (22)	41 (56)	NA
T9-T12	13 (18)	1 (1)	17 (23)	42 (58)	NA
First rib	30 (41)	0 (0)	12 (17)	31 (42)	NA
Second rib	10 (14)	0 (0)	16 (22)	47 (64)	NA
Note: NA = Not applicable					

Table III.7. Muscle strength and endurance results

N (%)				
Strength				
Muscle group	Abnormal	Normal	Not tested	Missing
Upper trapezius	2 (3)	24 (32)	47 (64)	1 (1)
Middle trapezius	22 (30)	7 (10)	44 (59)	1 (1)
Lower trapezius	23 (31)	5 (7)	45 (61)	1 (1)
Rhomboids	26 (35)	3 (4)	43 (58)	2 (3)
Longissimus colli	8 (11)	6 (8)	59 (80)	1 (1)
Sternocleidomastoid	9 (12)	5 (7)	29 (80)	1 (1)
Endurance				
Neck flexor endurance test	29 (40)	12 (16)	32 (44)	NA
Note: NA = Not applicable				

CHAPTER IV

Measurement Properties of the Dizziness Handicap Inventory-Children and Adolescent (DHI-CA) in children and adolescents post-concussion

Abstract

Background. Up to 80% of individuals report having dizziness post-concussion. Dizziness has been identified as a predictor of prolonged recovery post-concussion and it impacts activities and participation in post-concussed children and adolescents. Dizziness Handicap Inventory – children and adolescents (DHI-CA) was recently developed to evaluate impact of dizziness on activity and participation in children and adolescents with dizziness.

Purpose. The purpose of this study was to examine and report the psychometric properties of the DHI-CA in post-concussion children and adolescents.

Study design. Retrospective study

Methods. A retrospective chart review was conducted for 132 consecutive children and adolescents who received vestibular physical therapy post-concussion. Data was extracted on various outcome measures including DHI-CA, sports concussion assessment tool -III (SCAT III), vestibulo-ocular motor screen (VOMS) and patient-reported percent of recovery. The DHI-CA was examined for validity, factor structure, responsiveness and internal consistency.

Results. The DHI-CA demonstrated convergent validity by demonstrating statistically significant relationship with the SCAT-III symptoms related to dizziness ($r_s = 0.30-0.40$). The DHI-CA failed to demonstrate discriminant validity and showed limited diagnostic ability to discriminate between individuals who did or did not show clinically meaningful improvements. On factor analysis, structural inconsistencies were noted as the items demonstrated cross loading and an overall poor model fit was indicated (RMSEA = 0.105).

Conclusion. Despite demonstrating convergent validity, DHI-CA demonstrated limited discriminant validity and responsiveness along with significant structural limitations in the factor structure. Hence, caution is recommended while making clinical decisions based on the DHI-CA results.

Clinical relevance. This study indicates the need to revise the DHI-CA and reevaluate the psychometric properties in post-concussion children and adolescents before it can be utilized in clinical settings to evaluate the impact of dizziness following a concussion in this population.

Key words. Concussion, youth, dizziness adolescents

Introduction

Dizziness is a non-specific term that includes symptoms anywhere from disorientation and lightheadedness to vertigo and imbalance^{1,2}. Dizziness has been reported by up to 80% of the individuals post-concussion.³ Both vestibular and cervical spine involvement contribute towards lasting dizziness post-concussion.⁴ Dizziness has also been reported to be associated with whiplash-associated disorders (WAD).⁵ This may be attributed to abnormal input from the cervical spine secondary to damage in muscle and joint receptors.⁵ Post-concussion, the natural course of recovery from dizziness is longer as compared to the non-dizziness oriented symptoms and may last ranging from 6 months up to 5 years after the event.^{1,3}

Dizziness at the time of injury has been identified as a predictor (Odd's ratio = 6.34 (1.34-29.91)) for longer recovery times in post concussed athletes.⁶ Post-concussion dizziness can negatively impact the life of an individual in regards to participation in sports, activities of daily living, socializing and overall quality of life (QOL).⁷ There is emerging evidence that the incidence of concussion among children and adolescents is rising. Despite this, currently available self-reported assessment methods for dizziness are developed for adult population. There is limited information on dizziness related outcome measures in children and adolescents. Although several self-reported outcome measures to assess dizziness are currently available for the adult population, information on assessment methods is still scarce in the children and adolescents.⁸

Of the available outcome measures for dizziness, the Dizziness Handicap Inventory (DHI) is the most widely used self-assessment inventory for evaluating precipitating physical, emotional and functional factors that are associated with dizziness.^{9,10} The DHI was developed

from the hearing handicap inventory for the elderly.⁹ The DHI is an ordinal scale that consists of 25 items and a total score of 0-100 points with higher scores indicating more severe impairment.⁹ The DHI has been used by multiple rehabilitation professionals to evaluate activity limitations and participation restriction, formulate therapeutic goals, plan of care and intervention strategies in adults with dizziness.¹¹ The DHI has been adapted in several languages and for different age groups.¹¹⁻¹⁴

Recently, DeSoussa and colleagues adapted the Brazilian Portuguese version of the adult DHI to the children and adolescent population which was named DHI- children and adolescent (DHI-CA).⁸ Internal consistency was reported for the overall DHI-CA (Cronbach's $\alpha = 0.84$) and each subscale (Cronbach's $\alpha = 0.70$ for emotional, Cronbach's $\alpha = 0.66$ for functional and Cronbach's $\alpha = 0.62$ for physical subscale) in 6-14 year old children with dizziness.⁸

Psychometric properties of the DHI-CA have not been studied in the subset of post-concussion children and adolescents. Given the need for valid instruments to assess dizziness in this population, the purpose of this study was to examine and report the psychometric properties of the DHI-CA in post-concussion children and adolescents. The specific aims of this study were 1) to examine the construct validity (convergent and discriminant), 2) to examine the structure of items within the DHI-CA to report the nature of their inter-relationships and 3) to examine responsiveness of the DHI-CA and 4) to describe the internal consistency of the DHI-CA in post-concussion children and adolescents.

Methods

Design, setting and participants

The data for this study was collected retrospectively from the electronic medical records of a tertiary center specializing in comprehensive interdisciplinary management of patients with concussion. The study was approved by the Institutional Review Board of the primary investigator's institution. A retrospective chart review was conducted for 132 children and adolescents between the ages of 8 to 18 years who received vestibular physical therapy following a concussion.

Data extraction

A data extraction sheet was developed by two investigators (DT and BA). The investigators independently extracted data for 10 random patients and the extracted data was compared to ensure consistency in data extraction. After ensuring quality of the extracted data, the primary investigator (DT) completed the remaining data collection with random audits by the secondary investigator (BA).

Data obtained from physician visits

Demographic, injury and care process data. Demographic and injury characteristics were retrieved from electronic medical records. These characteristics included age, gender, primary sport(s), prior history of migraine or prior learning disabilities, date of sustaining concussion and mechanism of injury. In addition, the date of first medical visit, date of first physical therapy visit, total number of physician visits and total number of vestibular physical therapy visits were also collected to describe the care process.

The Sports Concussion Assessment Tool -3rd edition (SCAT-III). SCAT-III is a concussion evaluation tool that was developed from the original SCAT to make decisions regarding return to play.¹⁵ The data on symptom severity score was collected on 22 concussion related symptoms including cognitive, physical, sleep and affect related symptoms using a Likert scale (0 = none, 6 = severe), where higher scores indicated greater symptom severity (maximum possible score = 132).¹⁶ For the purpose of this study, the SCAT-III data from physician initial evaluation and discharge visit were utilized. Data on the individual symptoms such as balance problems, dizziness, feeling like “in a fog”, headache, sensitivity to light and sensitivity to sound, difficulty in concentrating, difficulty in remembering, nervousness or anxiety, irritability, sadness and neck pain was extracted as well.

Data obtained during vestibular physical therapy visit

Assessment data on various outcome measures from the initial vestibular physical therapy evaluation and discharge visit was extracted. In the event that a full assessment was not completed due to an aggravation of patient’s symptoms, the subsequent two visits were screened to extract additional assessment data.

Dizziness Handicap Inventory- Children & Adolescent (DHI-CA). The DHI-CA was administered on the first and last vestibular physical therapy visits. The data on DHI-CA was extracted from the first and final vestibular PT visits. The DHI-CA consists of 25 questions that are organized into three subscales i.e. functional (9 items), emotional (9 items) and physical (7 items). Each item on the scale is scored on a 3-point Likert scale, where “no” is no dizziness, 2 is “sometimes” and 4 is answered as “always” for dizziness (Appendix IV A).⁸ The DHI-CA was administered on the first and second vestibular physical therapy visits and at discharge from

vestibular PT. Data on total score and individual items of DHI-CA was extracted from vestibular physical therapy visit and the discharge visit.

Vestibulo-ocular motor screening (VOMS). The VOMS was designed to evaluate vestibular and ocular motor impairments via patient-reported symptom provocation following each assessment.¹⁷ The VOMS involves seven assessment categories which are smooth pursuit, horizontal and vertical saccades, convergence, horizontal and vertical vestibular-ocular reflex (VOR) and visual motion sensitivity (VMS).¹⁷ Following each assessment, the patient reports changes in headache, dizziness, nausea and foggiess as compared to baseline values.¹⁷ In addition to symptom provocation, the near point convergence (NPC) distance is measured (cm). The VOMS has been reported to demonstrate high internal consistency (Cronbach' $\alpha = 0.97$)¹⁸ and acceptable construct validity ($r_s = 0.25-0.66$, $p \leq 0.02$)¹⁹ in children and adolescents. The VOMS has been reported to be a predictor of recovery time in children and adolescents with concussion.²⁰ The change score of dizziness after performing maneuvers including smooth pursuits, horizontal & vertical saccades, horizontal and vertical VOR, VMS and convergence were used to examine convergent validity.

Percent of recovery. Patient-reported percentage of recovery values (out of 100) were quantified at vestibular physical therapy visits. Change in percentage of recovery between first and last vestibular PT visit was computed. An improvement by 15% was considered as clinically meaningful. Global rating of change (GROC) has been utilized previously as an anchor-based method for evaluating responsiveness. However, since GROC is scored using only 7 points, it is challenging capture smaller but meaningful changes given the arbitrary choice of options such as “little bit better or worse”.²¹ Since a point change in score in GROC is considered clinically significant (considering a score of 7 representing 100% improvement), a 15% improvement was

used as the anchor as it may correspond to a one-point improvement in the global rating of change scale assuming that the score of 7 represents 100% recovery.^{22,23}

Statistical Analysis

The demographic, injury and process of care data was expressed using descriptive statistics. The DHI-CA scores were evaluated for normality using Kolmogorov-Smirnov test.

Validity

Convergent and discriminant validity. Construct validity demonstrates the ability of an instrument to measure an abstract concept.²⁴ To examine the convergent validity of the DHI-CA, it was validated against the total SCAT-III score and specific SCAT- III symptoms (balance problems, dizziness, feeling like “in a fog”, headache, sensitivity to light and sensitivity to sound), dizziness provocation in each of the seven VOMS items and the NPC distance was collected at initial evaluation. For discriminant validity, associations between DHI-CA scores and unrelated constructs identified from the SCAT- III (difficulty in concentrating, difficulty in remembering, nervousness or anxiety, irritability, sadness and neck pain) were examined.

Spearman’s rho (r_s) was used to examine convergent and discriminant validity. Interpretation of correlation coefficients followed guidelines where coefficients exceeding 0.75 indicate good to excellent relationship, coefficients between 0.50-0.75 indicate moderate to good relationship, coefficients between 0.25-0.50 indicate fair relationship and coefficients between 0.00-0.25 indicate little or no relationship.²⁴

Factor analysis. An exploratory factor analysis (EFA) was performed to reveal the underlying structures of the DHI-CA items. Also, a confirmatory factor analysis (CFA) was performed to examine whether the factors of the DHI-CA that emerged fit with the previously

explained components (physical, emotional and functional). CFA is an accepted method to evaluate and refine existing outcome measures.²⁵

For this purpose, the DHI-CA data from initial vestibular physical therapy visit was utilized. An EFA was performed on all 25 items of the DHI-CA using principal component analysis (PCA) with oblique rotation to reveal patterns of relationship among the items. First, an inter-item correlation matrix was created for all the DHI-CA items. The model was forced to retain three factors. Factor loadings greater than 0.4 were considered indicative of some degree of relationship and loadings ≥ 0.32 on two or more factors were considered as indicators of cross loading.^{24,26} Items that highly loaded on one factor were grouped together. Factor loading values were inspected to identify cross loading of items. Since, the factors were correlated, oblique rotation was chosen as described by Portney & Watkins.²⁴

A CFA using structural equation modeling was performed to examine whether the relationships expected on theoretical constructs that were obtained from the EFA actually appeared in the data.²⁵ Based on the factors obtained from the EFA, all the items were entered in the structural equation modeling. Model fit was evaluated using Chi-square test (non-significant results i.e. $p < 0.05$ indicating a good model fit),²⁷ and the root mean square error of approximation (RMSEA). RMSEA is considered as the gold standard for testing goodness of fit as unlike Chi-square test, RMSEA is not influenced by the sample size.²⁸ The RMSEA values ≤ 0.10 were considered acceptable with values between 0.0-0.05 indicating a close fit and values between 0.05-0.08 indicating a reasonable fit.²⁷

Responsiveness. Responsiveness is defined as the ability of an instrument to accurately detect change when it has occurred.²⁴ To determine responsiveness, the change in DHI-CA scores from initial and final vestibular PT visits was measured against the difference in patient-

reported percent of recovery between initial and final vestibular PT visits. A clinically meaningful change was operationally defined as a 15 % difference in the patient reported recovery.

Responsiveness was determined by using both distribution and anchor-based methods. Both effect size (ES) using Cohen's D and standardized response mean (SRM) were used as distribution-based methods. Cohen's D was calculated using the formula $ES = (M_1 - M_2) / SD_2$ (M_1 = Mean DHI- CA score post vestibular PT, M_2 = Mean DHI- CA score pre vestibular PT, SD_1 = Standard deviation post vestibular PT, SD_2 = Standard deviation pre vestibular PT) whereas SRM was calculated using the formula $SRM = (M_1 - M_2) / SD_{\text{change}}$ (SD_{change} = Standard deviation of change scores).²⁴ Wilcoxon signed ranked test was used to determine pre to post physical therapy change in the DHI-CA scores.²⁴

Anchor-based method using patient reported percent of recovery values was used to evaluate patient's perception of their recovery status following physical therapy interventions. Additionally, a receiver operating characteristics (ROC) curve was utilized to evaluate the ability of the DHI-CA to identify patients who improved significantly based on the patient reported percent of recovery values (improvement of 15% or more). The area under the curve (AUC) was computed and the cutoff points for the minimally clinically important difference (MCID) were determined from the point on the ROC curve that was closest to the top left corner. The MCID was determined as the best cut-off point identified on the ROC curve to discriminate between the participants who improved and those who did not improve. AUC values of > 0.70 were considered as adequate for making this determination.²⁹

Internal consistency. To determine reliability of the DHI-CA items, internal consistency was examined. Internal consistency is a measure of the extent to which all the items in the

outcome measure address the same underlying concept.²⁴ The DHI-CA data collected at the initial vestibular physical therapy visit was utilized for assessment of internal consistency.

Cronbach's alpha was used to examine internal consistency of the DHI-CA. Item to total correlations were performed where each item was correlated with the total score, omitting that individual item from the total score.²⁴ Cronbach's alpha values ranging from 0.70-0.90 were considered indicative of strong internal consistency.²⁴

Analyses were performed using Statistical Package for Social Sciences (SPSS) version 24.0 (SPSS Inc., Armonk, NY) and STATA version 15.0 (StataCorp LLC, College Station, Texas). The level of significance was set at 0.05.

Results

Demographics, mechanism of injury and process of care

Data on 132 children and adolescents between the ages of 8 to 18 years received vestibular physical therapy following a concussion between January 2017 and February 2018 was collected. Since, the missing data within the sample was less than 10% of the total data, adjustments for missing data were not performed.³⁰ The average age of patients was 15.3 ± 2.1 years (40.2% males). Nineteen percent of patients sustained concussion after contacting the playing surface, 34% of the injuries were resulted from contact with another player whereas 22% of patients sustained injury from coming into contact with sporting equipment. Mechanism of injury was not sport-related for 23% of patients ([Table IV.1](#)).

Thirty-three percent of patients had a history of migraine, 9% had attention deficit, 13.6% had learning disability whereas 9% of patients had attention deficit hyperactivity disorder. The median time to first physician visit following injury was 16 days and the median time taken for physical therapy evaluation following their first physician visit was 28 days ([Table IV.1](#)).

Validity

Convergent validity. Fair positive relationship was observed between the DHI-CA total scores and SCAT-III total score ($r_s = 0.45$, $p < 0.001$) and the SCAT-III items with the highest value for dizziness ($r_s = 0.40$, $p < 0.001$) and the lowest value for sensitivity to light ($r_s = 0.30$, $p = 0.001$) thereby demonstrating an increased perception of disability with an increase in symptoms. Similarly, fair positive relationship was observed between the DHI-CA and dizziness scores on all seven assessment categories of the VOMS (initial vestibular PT evaluation) with highest value for NPC ($r_s = 0.48$, $p < 0.001$) and the lowest value for visual motion sensitivity (r_s

= 0.38, $p < 0.001$) indicating increased perceived disability with increased VOMS scores ([Table IV. 3](#)). The DHI-CA did not demonstrate a statistically significant relationship with average NPC distance scores ($r_s = 0.20$, $p = 0.134$) ([Table IV.2](#) & [Table IV.3](#)).

Discriminant validity. The DHI-CA lacked discriminant validity as it demonstrated statistically significant positive relationship with all of the selected SCAT-III items that were unrelated to the construct of dizziness (cognitive and affective symptoms). Difficulty in remembering demonstrated the highest correlation value ($r_s = 0.33$, $p < 0.001$) whereas irritability demonstrated the lowest correlation values ($r_s = 0.21$, $p = 0.02$) indicating possible contribution of cognitive and affective symptoms towards perception of disability post-concussion ([Table IV.2](#)).

Factor Analysis. The EFA revealed six factors with eigenvalues > 1 of which the top 3 factors explained 52% of the variance. The scree plot ([Figure IV.1](#)) also indicated three obvious factor patterns to be retained for rotation. Based on this, a 3-factor solution was performed. Bartlett's test was significant ($p < 0.001$) and Kaiser Meyer Olkin measure of sampling adequacy (KMO) value was 0.832 (values > 0.5 are considered acceptable) indicating that the items were appropriate to be entered into factor analysis.³¹

Insert figure IV.1 here

Out of the three factors, factor 1 explained the most variance (32.3%). Factor 1 comprised of items that were originally included in the emotional subscale except item 18 (because of dizziness, do you have difficulty with concentrating on your school activities) which demonstrated better loading on factor 2. Factor 2 consisted of items that were described in the physical subscale except for item 17 (does walking on the sidewalk, passing or going over a

ground full of holes worsen the dizziness) which demonstrated better loading with factor 1. Factor 3 consisted of only three items and explained the least variance in the model (8.26%). Items that were included in this factor are described in the functional subscale of the DHI-CA (item 3, item 6 and item 24) ([Table IV.4](#)).

Other items of the functional subscale demonstrated better loadings with either factor 1 (item 16: because of the dizziness it is too difficult for you to walk about alone and item 19: because of the dizziness, are you unable to walk about in the dark) or factor 2 (item 5: because of the dizziness, do you have difficulty with getting up from the bed, item 7: because of the dizziness, do you have difficulty with reading, item 12: because of the dizziness, do you stay away from the high places and item 14: because of the dizziness, do you find it difficult to jump, run, play ball games, ride a bicycle?). Cross loading was noted for four items (items 18, 21, 23 & 24). The EFA resulted in component matrices as shown in [Table IV. 4](#).

In terms of the CFA, the goodness of fit statistics suggested an overall poor model fit. The chi-square test was significant indicating a poor model fit.²⁷ The RMSEA value of 0.105 was greater than the cutoff value for acceptable fit.²⁷ Other indicators of model fit such as the comparative fit index (CFI) = 0.733 (CFI > 0.95 indicate good model fit), Tucker Lewis index (TLI) = 0.706 (TLI > 0.95 indicate good model fit) and size of residuals = 0.098, all suggested that the model was a poor fit.²⁷

Responsiveness. Significant decrease was observed in the DHI-CA scores following physical therapy interventions (mean score pre = 26.6 ± 17.7 , mean score post = 10.7 ± 15 , $Z = -8.314$, $p < 0.001$). The ES (Cohen's D) and SRM for the DHI-CA were found to be 0.83 and 5.49 respectively indicating a large effect size. The MCID calculated from the ROC curve (AUC =

0.65, confidence interval = 0.53 – 0.76, $p = 0.004$) for the total DHI-CA score was 25 points (sensitivity = 68%, specificity = 58%). ([Figure IV.2](#))

Insert figure IV.2 here

Reliability analysis

Internal consistency. The overall internal consistency of the DHI-CA was found to be strong (Cronbach's $\alpha = 0.91$). Strong internal consistency was also found across all the sub-domains (Cronbach's $\alpha = 0.82$ (physical), 0.80 (emotional) and 0.81 (functional)). Corrected item-total correlation ranged from 0.31 to 0.65 with item 3 demonstrating the lowest and item 10 demonstrating the highest correlation values. The internal consistency of individual subscales and item to total correlations are reported in [table IV.5](#).

Discussion

To the author's knowledge, this is the first study to evaluate the validity and responsiveness of the DHI-CA in this population subset of children and adolescent post-concussion. The results from this study revealed that even though the DHI-CA demonstrated fair convergent validity, it failed to demonstrate discriminant validity. Moreover, it was found that the factor analysis revealed a different factor structure than originally described and a poor model fit was observed. Additionally, the DHI-CA demonstrated inadequate AUC based on previous recommendations^{29,32} indicating limited diagnostic abilities in identifying patients that demonstrated clinically meaningful improvement. High Cronbach's α values were observed for all three subscales and overall scale.

Although the DHI-CA demonstrated fair relationship with dizziness items of the SCAT-III (balance problems, dizziness, feeling like in a fog, sensitivity to light and sensitivity to sound) and dizziness scores from all components of VOMS, it failed to demonstrate a significant relationship with the average NPC distance. NPC distance has been identified as a measure of vestibulo-ocular function and a diagnostic tool to discriminate between presence and absence of concussion.¹⁷ An abnormality in the NPC distance has been reported to exist even in healthy adolescent population and it is recommended that screening for NPC distance prior to injury could provide more confidence in its diagnostic utility.¹⁹ Examining NPC does not involve head movements whereas most of the items on the DHI-CA consist of activities that require some degree of head movement. Additionally, the NPC utilizes double vision to evaluate convergence insufficiency,³³ and none of the DHI-CA items discuss double vision. These differences may explain the lack of relationship between the NPC and the DHI-CA.

The DHI-CA demonstrated poor discriminant validity as significant relationship was observed with cognitive and affective symptoms that are not theoretically related to the construct of dizziness.³⁴ On the other hand, it may be argued that the symptoms such as difficulty in concentrating and remembering may be a sequelae of dizziness and since the DHI-CA items have similar contents that include the ability to concentrate (item 7) and read (item 18), an association was observed.

Since, the original version of the DHI-CA was adapted from the adult version retaining all the original items within the pre-specified sub-scales i.e. physical, emotional and functional, an EFA was first performed in this study to explore how well the items fit in each subscale before examining its validity further. When the factor structure of a scale has not been determined, performing an EFA is recommended.²⁶ The results of the EFA indicated a different factor structure as compared to the original version of the DHI-CA as well as to adult DHI versions. Previous studies have reported of inconsistencies in terms of item loadings on to the factors as originally described in the DHI for adults who experienced dizziness secondary either to vestibular or non-vestibular causes.^{26,35} The findings from this study concur with the previous literature. Considering the possible limitations in item construction, and/or inaccuracies in the initial factor structure, restructuring of the DHI-CA for post-concussion population subset may be considered.

The loading pattern of the items in this study was similar to a previous study by Perez and colleagues on the original DHI where items under the emotional sub-scale demonstrated best loadings together and items in functional subscale demonstrated a scattered loading pattern.³⁵ Related activities (item 5: getting up from bed and item 13: turning in bed; item 8: jumping, running, riding a bicycle and item 14: riding a bicycle, games, sports) were placed in

different sub-scales in the DHI-CA. The results from the EFA in this study suggested grouping these items together. All of these items measure functional activities and it is postulated that a better structure could be obtained if these items were grouped under the same factor.

In addition, to examine if the newly identified item distribution actually conformed well to the three factors, a CFA was performed. The results from the CFA demonstrated a poor model fit warranting further exploration and revision of the item distribution in the scale. Several explanations for this finding are possible. Multiple items demonstrated cross loadings across the factors indicating item redundancy which may have resulted in a poor overall model fit.

The other possible explanation could be that the study was underpowered for the assessment of CFA. A sample size of > 200 has been recommended to obtain adequate power for the CFA.³⁶ Although, a priori sample size calculation indicated the requirement of 250 participants based on a participant to item ratio of 10:1 for the purpose of CFA,^{36,37} the retrospective chart review revealed only 132 participants that met the inclusion criteria within the specified timeline approved to review for the purpose of the study.

Additionally, the assumption of local independence for the CFA was not met in this study as the items in different factors demonstrated statistically significant correlation with each other.³⁸ Also, since the DHI-CA is scored on a Likert scale, transformation could not be performed to obtain normal distribution of the data. Hence, the utility of CFA was limited in identifying an appropriate model fit in this study. Previous studies that were done on original DHI and its adapted versions also performed factor analysis and failed to completely support the original structure.^{12,26,35} This finding is consistent with our study as the distribution of the items do not completely fit in the originally described structure.

The DHI-CA demonstrated poor ability to accurately identify the individuals who showed clinically meaningful improvement. The best cut-off point was found to be a score of 25 (sensitivity = 68%, specificity = 58%). The subjective nature of the DHI-CA may explain its limited ability in accurately predicting those who would improve. Percentage of recovery is not a specific question and is open to various interpretations. This is particularly true given the multifaceted effects of concussion. Even though, the patient may get better with dizziness, their perception of recovery can be hampered by other factors such as cognitive deficits, cervical spine deficits, or restricted participation in sport/school.

Another explanation could be that although the scale is scored on a total of 100 points, each item is scored on a Likert scale of 0, 2 and 4. This scoring system may not be adequate to capture small but meaningful changes in patient condition as the options the patients can choose from are very limited. For e.g. in a 0-10 scale, a continuum of improvement/decline can be captured. However, since the interval from 0 (no) to 2 (sometimes) to 4 (yes) is quite large, an individual who started out at 4 and may have shown a small improvement, still might not consider it an improvement big enough to be classified under 2. This inability of DHI-CA to capture the continuum of improvement may have potentially created an ambiguity and affected the responses.

The results of this study revealed a large effect size indicating a significant decline in DHI-CA scores following physical therapy intervention. This was in contrast to the findings noted by the anchor-based methods. Although distribution-based methods such as effect size provide a statistical measure to identify change irrespective of the variations in sample size, it is strongly influenced by the characteristics such as normal distribution and homogeneity at baseline.^{39,40} The non-normal distribution of the sample in this study could have affected the

findings of the test. Another limitation of effect size lies in the lack of its ability to provide a good sense of clinical relevance of change. The use of the cut points provided by effect size in establishing clinically significant improvement are debatable in literature,^{39,41} further suggesting that the effect size is questionable in determining clinically meaningful change.

The findings on internal consistency were similar to the results reported by DeSousa et al.⁸ Previous literature recommends that a maximum value of 0.9 for Cronbach's α is indicative of strong internal consistency.^{24,42} Values greater than 0.9 have been reported to indicate that the relationship among the items may be too high. This could suggest that the items may be redundant and testing the same question in a different way.^{24,42} The high overall Cronbach's α (0.91) in this study may suggest reviewing the DHI-CA for possible item reduction.

Limitations. The authors recognize the limitations of this study. Although the DHI-CA was assessed for validity using other subjective and clinical measures, objective measures including instrumented measures of vestibular dysfunction was not utilized. Future studies may consider validating this tool using instrumented measures such as video head impulse test, vestibular-evoked myogenic potentials and caloric testing.

The retrospective design of the study limited the ability to ascertain if the patients received assistance from the parents or therapists in completing the DHI-CA. Differences in the level of assistance received in filling out the questionnaire may have influenced the responses.

Although the study was adequately powered for internal consistency and validity analysis,²⁹ it was underpowered for the CFA and future studies with larger sample sizes are recommended.

Cross loading of items evidenced on EFA along with high overall Cronbach's α indicate a need for revision of the DHI-CA and further validation. Given that the ordinal nature of DHI-

CA and correlation between the items belonging to different subscales violate the assumptions of local independence for CFA, an item response theory (IRT) using Rasch analysis is recommended to conform and revise the scale.

Conclusion

The DHI-CA did demonstrate convergent validity but failed to demonstrate discriminant validity. Structural inconsistencies on factor analysis and possible item redundancy as indicated by the overall Cronbach's α value warrant further exploration and possible re-structuring of the DHI-CA using item response theory/Rasch analysis. Additionally, considering inadequate diagnostic ability of the DHI-CA along with the aforementioned limitations, caution is recommended when considering making clinical decisions based on DHI-CA in children and adolescents post-concussion. Additionally, limitations of study design and sample limit the generalizability of findings. Hence, further research to revise the scale and further explore its psychometric properties is recommended.

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Figure IV.1. Scree plot indicating factors to be retained

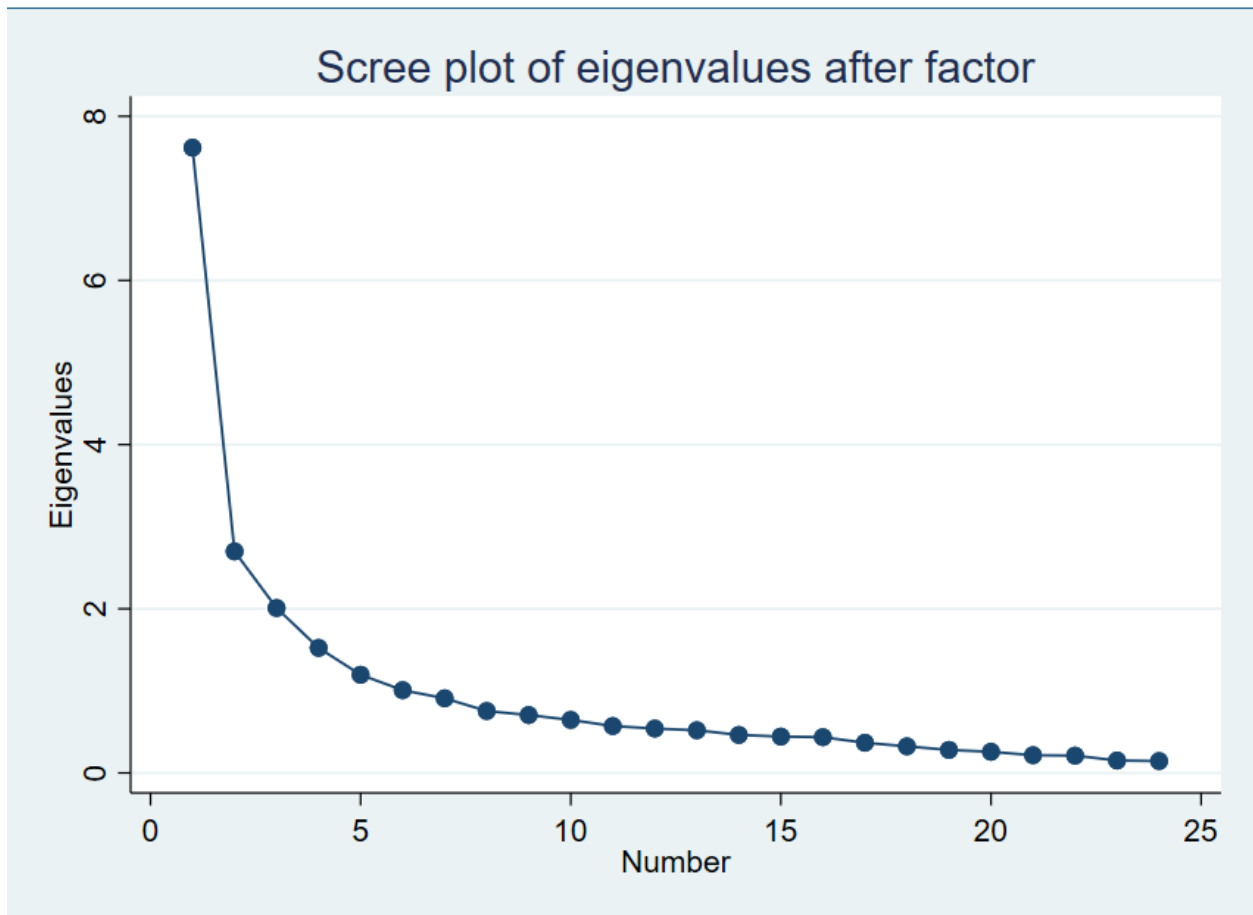
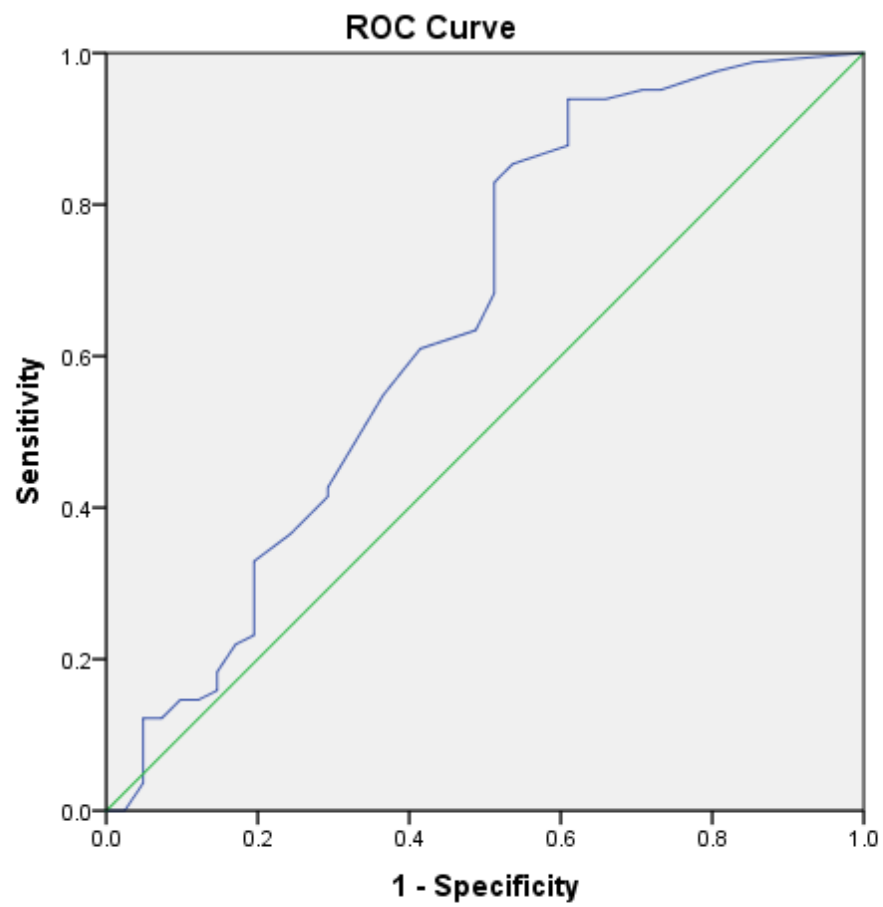


Figure IV.2. Receiver operating characteristic (ROC) curve



Diagonal segments are produced by ties.

Table IV.1 Demographic, injury and care characteristics of participants

N (% males)	53 (40.2)
Age in years, mean (SD)	15.3 (2.1)
Attention deficit, n (%)	12 (9.1)
Attention deficit hyperactivity disorder, n (%)	12 (9.1)
Learning disability, n (%)	18(13.6)
History of migraine, n (%)	33 (25)
Mechanism of injury N (%)	
Contact with another player	45 (34)
Contact with playing surface	25 (19)
Contact with sporting equipment	29 (22)
Others (Non-sport related)	30 (23)
Not specified	3 (2)
Process of care, Median (Min – Max)	
Days to first physician visit following concussion	16 (1-479)
Days to first PT visit following physician visit	28 (5-550)
Number of physician visits	4 (1-12)
Number of physical therapy visits	3 (1-11)

Table IV.2. Relationship between Dizziness Handicap Inventory-Children and Adolescents (DHI-CA) & SCAT III measures and Near point convergence (NPC)

DHI-CA symptoms (N)	Spearman's rho (p-value)
Balance problems (124)	0.37 (<0.001)
Dizziness (124)	0.40 (<0.001)
Feeling like in a fog (124)	0.39 (<0.001)
Headache (124)	0.17 (0.056)
Sensitivity to light (124)	0.30 (0.001)
Sensitivity to sound (124)	0.38 (<0.001)
SCAT-III total score	0.45 (<0.001)
Difficulty in concentrating (124)	0.31 (<0.001)
Difficulty in remembering (124)	0.33 (<0.001)
Nervousness or anxiety (124)	0.25 (0.006)
Neck pain (124)	0.26 (0.004)
Irritability (124)	0.21 (0.020)
Sadness (124)	0.28 (0.001)
Average NPC scores (56)	0.20 (0.134)

SCAT III = sports concussion assessment tool III 3rd edition, NPC = Near point convergence, VOR = Vestibulo-ocular reflex

Table IV.3. Relationship between Dizziness Handicap Inventory-Children and Adolescents (DHI-CA) and dizziness scores VOMS at initial vestibular physical therapy evaluation

VOMS symptoms	Spearman's rho (p-value); N						
	Smooth pursuit	Horizontal Saccads	Vertical Saccads	Convergence	VOR horizontal	VOR vertical	Visual motion sensitivity
Dizziness	0.41 (p < 0.001); 125	0.39 (p < 0.001); 126	0.42 (p < 0.001); 126	0.48 (p < 0.001); 122	0.43 (p < 0.001); 125	0.39 (p < 0.001); 121	0.38 (p < 0.001); 122

VOMS = Vestibular-Ocular Motor screening, VOR = Vestibulo-ocular reflex

Table IV.4. Exploratory factor analysis of the DHI-CA

Factor 1		Factor 2		Factor 3	
Item	Loading value	Item	Loading value	Item	Loading value
Item 9	0.82	Item 8	0.78	Item 3	0.71
Item 10	0.81	Item 11	0.78	Item 6	0.62
Item 15	0.80	Item 14	0.71	Item 24	0.47
Item 16	0.68	Item 7	0.70		
Item 17	0.65	Item 1	0.64		
Item 19	0.64	Item 13	0.61		
Item 20	0.62	Item 5	0.61		
Item 22	0.61	Item 18	0.60		
Item 23	0.54	Item 25	0.57		
Item 2	0.43	Item 4	0.54		
Item 21	0.40				

Table IV.5. Internal consistency of the DHI-CA

Item number	Item description	Median (Range)	Corrected item-total correlation	Cronbach's α if item is deleted
	Physical (Cronbach's $\alpha = 0.82$)			
1	Does lifting your head up worsen dizziness?	2 (0-4)	0.64	0.78
4	Does walking around the supermarket looking at the shelves worsen the dizziness?	0 (0-4)	0.54	0.79
8	Do games, sports, riding a bicycle, riding on roundabouts/merry-go-rounds worsen the dizziness?	2 (0-4)	0.57	0.79
11	Do fast movements of the head worsen your dizziness?	2 (0-4)	0.64	0.77
13	If you turn in bed while you are lying down (a) does it worsen your dizziness?	0 (0-4)	0.58	0.79
17	Does walking on the sidewalk, passing or going over a ground full of holes worsen the dizziness?	0 (0-4)	0.41	0.81
25	If you lower your head or body, does the dizziness worsen?	2 (0-4)	0.54	0.79
	Emotional (Cronbach's $\alpha = 0.80$)			
2	Because of the dizziness, do you feel frustrated (a)?	2 (0-4)	0.51	0.78
9	Because of the dizziness, are you afraid to leave the house?	0 (0-4)	0.59	0.78
10	Because of the dizziness, do you feel ashamed (a) in front of others?	0 (0-4)	0.65	0.76
15	Because of the dizziness, are you afraid that people will think you are not well?	2 (0-4)	0.60	0.77
18	Because of the dizziness, do you have difficulty with concentrating on your school activities?	0 (0-4)	0.39	0.81
20	Because of the dizziness, are you afraid to stay at home alone?	0 (0-4)	0.40	0.80
21	Because of the dizziness, do you feel harmed (a) in comparison with your colleagues? / companions?	0 (0-4)	0.42	0.79
22	Because of the dizziness, do you quarrel with your friends, companions or persons in your family?	0 (0-4)	0.56	0.77
23	Because of the dizziness, do you feel sad, without wanting to do anything?	0 (0-4)	0.57	0.77
	Functional (Cronbach's $\alpha = 0.81$)			
3	Because of the dizziness, do you stay away from school?	0 (0-4)	0.31	0.81
5	Because of the dizziness, do you have difficulty with getting up from the bed?	2 (0-4)	0.42	0.80
6	Do you stay away from birthdays, parties, movies, video game arcades because of the dizziness?	0 (0-4)	0.54	0.78
7	Because of the dizziness, do you have difficulty with reading?	2 (0-4)	0.59	0.77
12	Because of the dizziness, do you stay away high places?	0 (0-4)	0.47	0.79
14	Because of the dizziness, do you find it difficult to jump, run, play ball games, ride a bicycle?	2 (0-4)	0.54	0.78
16	Because of the dizziness, it too difficult for you to walk about alone (a)?	0 (0-4)	0.52	0.79
19	Because of the dizziness, are you unable to walk about in the dark?	0 (0-4)	0.53	0.78
24	Does your dizziness hamper, interfere in your studies?	2 (0-4)	0.63	0.77

Appendix IVA. Dizziness Handicap Inventory – Children and adolescents (DHI-CA)

Subscales	Questions	Responses		
		Yes	Sometimes	No
1- Physical	Does lifting your head up worsen dizziness?			
2- Emotional	Because of the dizziness, do you feel frustrated (a)?			
3- Functional	Because of the dizziness do you stay away from school?			
4- Physical	Does walking around the supermarket looking at the shelves worsen the dizziness?			
5- Functional	Because of the dizziness, do you have difficulty with getting up from the bed?			
6- Functional	Do you stay away from birthdays, parties, movies, video game arcades because of the dizziness.			
7- Functional	Because of the dizziness, do you have difficulty with reading?			
8- Physical	Do games, sports, riding a bicycle, riding on roundabouts/merrygorounds worsen the dizziness?			
9 – Emotional	Because of the dizziness, are you afraid to leave the house?			
10 – Emotional	Because of the dizziness, do you feel ashamed (a) in front of others?			
11- Physical	Do fast movements of the head worsen your dizziness?			
12- Functional	Because of the dizziness, do you stay away high places?			
13 – Physical	If you turn in bed while you are lying down (a) does it worsen your dizziness?			
14 – Functional	Because of the dizziness, do you find it difficult to jump, run, play ball games, ride a bicycle?			
15 – Emotional	Because of the dizziness, are you afraid that people will think you are not well?			
16 – Functional	Because of the dizziness, it is difficult for you to walk about alone (a)?			
17 – Physical	Does walking on the sidewalk, passing or going over a ground full of holes worsen the dizziness?			
18 – Emotional	Because of the dizziness, do you have difficulty with concentrating on your school activities?			
19 – Functional	Because of the dizziness, are you unable to walk about in the dark?			
20 – Emotional	Because of the dizziness, are you afraid to stay at home alone?			
21 - Emotional	Because of the dizziness, do you feel harmed (a) in comparison with your colleagues?/ companions?			
22 – Emotional	Because of the dizziness, do you quarrel with your friends, companions or persons in your family?			
23 – Emotional	Because of the dizziness, do you feel sad, without wanting to do anything?			
24 – Functional	Does your dizziness hamper, interfere in your studies?			
25 – Physical	If you lower your head or body, does the dizziness worsen?			

Chapter V

Overview

The focus of this dissertation was to explore cervical spine impairments and evaluate measurement error of different assessments of postural control and to examine psychometric properties of the Dizziness Handicap Inventory-Children and Adolescents (DHI-CA) in children and adolescents post-concussion.

This dissertation utilized the three-paper method with three individual studies. Chapter I provides a general background on the focus of this dissertation. Chapter II discusses the measurement properties of postural control measures in typically developing children and adolescents. This review will contribute towards directing future studies towards validating these measures in children and adolescents post-concussion since typically developing population bears close resemblance to post-concussion population. Chapter III provides a detailed description on cervical spine impairments in children and adolescents post-concussion. Since majority of the research on concussion has been focused on professional and college athletes, the findings of this research will help to provide preliminary data to conduct further research for development of structured assessment for this subset of population post-concussion.

Chapter IV describes the final study of this dissertation that includes an assessment of the psychometric properties of the DHI-CA in children and adolescents post-concussion. This study will help to further the development of valid and reliable assessment of dizziness in this population subset. Since, dizziness has been reported to be negatively impacting the recovery time and quality of life post-concussion, a valid and responsive tool is required to evaluate dizziness post-concussion in this age range. DHI for adults has been validated in various populations and languages. Recently, a version of DHI was developed for children and

adolescents from the Brazilian-Portuguese version and was translated to English. However, this version has not yet been validated in post-concussion population.

This final chapter (Chapter V) summarizes the major findings of the three studies in this dissertation and their implications for future research. It also discusses the limitations of the research and how those limitations may have affected the results.

Summary of Research Design and Results

The following section describes a summary of the methods and results of the three individual studies in this dissertation.

Overview

Study 1

The primary purposes of this study were to conduct a systematic review to 1) report the test-retest, intra-rater and inter-rater reliability of postural control outcome measures, to 2) report the minimal detectable change and standard error of measurement (SEM) of these outcome measures and to 3) describe methodological and reporting qualities of the studies that examined the reliability of postural control outcome measures in typically developing children with a mean age of 8-18 years. The results of the electronic search identified 25 studies examining 22 (8 static, 14 dynamic) different postural control measures.

The findings of this review suggest that out of the the different static postural control measures identified, the BESS was widely studied and demonstrated acceptable reliability across all studies, indicating that this measure might be used for evaluation of static postural control in typically developing children. Among the instrumented static postural control measures, the CTSIB was found to demonstrate the highest reliability when used with the AccuGait force platform. Among the dynamic postural control measures, TUG demonstrated good reliability and can be used cautiously to evaluate dynamic postural control. Other measures including the

mFRT, one leg hop, BEST and mini BEST provide promising findings. However, observations from single reliability studies and methodological inconsistencies limited the ability to draw valid conclusions and make specific recommendations. Studies with stronger methodological design in future are needed to draw meaningful conclusions.

Study 2

This study was conducted to characterize the type, frequency and severity of cervical impairments in children and adolescents post-concussion. This study aimed at providing insights into the extent and nature of cervical spine impairments post-concussion that may provide a foundation to develop targeted physical therapy interventions. For this purpose, a retrospective chart review was performed on 73 patient charts to extract the assessment data from the first three physical therapy visits. Data was divided into five broad categories including posture, movement quality and generalized joint hypermobility; joint mobility (ROM, segmental mobility and pain with movement); myofascial tension to palpation; muscle strength & endurance and proprioceptive testing. The results of this study revealed high prevalence of cervical spine impairments with posture and myofascial impairments demonstrating highest impairment frequency.

Data on joint mobility revealed that 71% of the patients demonstrated impairments in upper cervical spine mobility. Additionally, out of all the muscles tested for strength, it was found that the rhomboids demonstrated highest frequency in terms of muscle weakness (35%). Poor neck flexor endurance was observed in 40% of the patients. It was also found that the joint position error testing, neck flexor endurance test and cranial cervical flexion test were not completed in majority of the patients. The results from this study contribute towards providing preliminary data to support the framework of a cervical spine evaluation tool in children and adolescents post-concussion. Further research is warranted in terms of developing population specific screening tools for cervical spine impairments post-concussion.

Study 3

The purpose of this study was to examine validity, factor structure, responsiveness and internal consistency of the DHI-CA in children and adolescents post-concussion. For this study, a retrospective chart review of 132 patients (8-18 years) who received vestibular physical therapy post-concussion was conducted and data was extracted. The results of this study indicated that the DHI-CA demonstrated fair convergent validity as significant correlations were observed with SCAT-III total scores ($r_s = 0.45, p < 0.001$), with SCAT-III items related to the construct of dizziness ($r_s = 0.30-0.40, p < 0.001$) and with components of VOMS ($r_s = 0.38-0.48, p < 0.001$). Poor discriminant validity was observed as the DHI-CA demonstrated significant relationship with the cognitive and affective symptoms of the SCAT-III. The DHI-CA demonstrated 68% sensitivity and 58% specificity and a score of 25 was established as the cut point. The DHI-CA demonstrated strong internal consistency for the subscales (Cronbach's $\alpha \geq 0.80$). However, the overall Cronbach's α was > 0.90 indicating possible item redundancy.

The results from the factor analysis revealed a different factor structure from what was described in the original scale and cross loading was observed in 4 items. Additionally, the confirmatory factor analysis CFA indicated an overall poor model fit. Findings of this study warrant further research in terms of subjecting the DHI-CA to item response theory and conducting a Rasch analysis to improve the scale structure.

Discussion of results

This dissertation reviewed measurement errors of postural control measures in typically developing children, cervical spine impairments post-concussion and examined psychometric properties of the DHI-CA in children and adolescents post-concussion.

Study one was conducted to provide a comprehensive overview of measurement errors of static and dynamic postural control measures in typically developing children. Since, typically developing children and adolescents demonstrate close resemblance to post-concussion population, it was important to evaluate measurement errors of postural control measures in typically developing population before they could be tested on post-concussion population which demonstrates higher variability in neuromotor function. Findings of this review will aid a clinician in becoming a well-informed consumer in terms of selecting a postural control measure to make informed clinical decision.

Findings from this review indicated that both instrumented and non-instrumented versions of the BESS demonstrated comparable reliability and could be used with caution in clinics.¹ In terms of instrumented measures, high variability was observed across force platforms in terms of reliability, which could be explained by the differences in foot placement and number of trials used. Other factors including foot placement, number of trials, fatigue, motivation of the participant and concentration may affect reliability.

Among the dynamic balance measures, TUG was the most studied measure and demonstrated acceptable reliability across studies. The ease of administration, simplicity of instructions and brevity of TUG could explain its higher reliability. Other measures such as mFRT, TUDS, BEST, miniBEST although demonstrated comparable findings, were reported

only in single studies and demonstrated several methodological inconsistencies limiting the ability to draw valid conclusions.

Overall, several inconsistencies in the quality of studies were noted across the studies that were included in this review. Inconsistencies in sample size and power estimation, lack of reporting of confidence intervals and inaccuracies in the type of the ICC model and form used limit the generalizability of the findings of this review to a broader range of population. Additionally, MDC was not calculated in 80% of the studies which further contribute towards limiting the clinical applicability of the included studies.

Study 2 discussed the impairments of the cervical spine in children and adolescents post-concussion. High prevalence of cervical spine impairments was observed in this study with over 90% of patients demonstrating impairments in 3 or more categories. Muscle tension, joint mobility and muscle strength were the categories demonstrating highest frequency of impairment. The categories of impairments examined in this cohort are consistent with the impairments reported in the most recent clinical practice guidelines for neck pain. Previous literature has affirmed that contribution of the cervical spine to various concussion symptoms such as headaches and dizziness.²⁻⁴

Over 85% of the patients demonstrated impairments joint mobility with upper cervical spine showing most restriction in mobility. Mobility impairments in the cervical spine and increased muscle tension and impaired joint proprioception in the cervical spine have been reported to contribute towards symptoms such as headache and dizziness post-concussion.^{2,3,5,6} It is noteworthy that muscle strength and joint proprioception were not tested in more than 50% of the patients thereby leading to potential under-representation of these impairments. Acute nature of symptoms may explain under-utilization of these tests in this sample. Additionally, 40% of the

patients reported moderate to severe disability on the NDI. It is noteworthy that the NDI has not been validated for population below 18 years of age thereby warranting further research. Despite of the potential sample bias, this study provides a foundation on which further research can be built upon to develop targeted assessment tools and intervention strategies.

The third study aimed at examining, validity, factor structure, responsiveness and internal consistency of the DHI-CA in post-concussion population. Limited diagnostic abilities of this scale were observed in this study. The DHI-CA demonstrated fair convergent validity but failed to demonstrate discriminant validity. Very high values of the Cronbach's α indicate a potential for item redundancy. This could be explained by similarity in the item descriptions and activities included in the individual items. Also, it is difficult to distinguish if the difficulty experienced by the patients in activities of daily living are due to dizziness or from other symptoms related to concussion. The factor structure and item distribution in the DHI-CA was kept same as that of the adult version. Results from the EFA indicate that there is a possibility that the items should be loaded under different factors as compared to the original version since the same factor distribution may not be appropriate for the population that is considered in this study.

Limitations

Several limitations were associated with this dissertation. The systematic review revealed a variety of outcome measures to examine postural control in typically developing children. Although an extensive electronic and manual search was conducted, the search was limited to studies that were published in the English language, and those that were published in peer reviewed journals. The possibility of having missed good quality studies for these resources cannot be ruled out. Additionally, heterogeneity in the sample size, limited number of studies and methodological inconsistencies across the studies limited the generalizability of the results from this review.

The sample for studies 2 and 3 were drawn from a single tertiary clinic, thereby creating a potential for sample bias as this sample might not be an adequate representation of the entire spectrum of children and adolescents post-concussion. Additionally, the retrospective study design used in this dissertation limited the control on the way the data was collected and recorded. There was missing data on several variables of interests that limited the availability of the data thereby potentially affecting the generalizability of the results. In study 2, subjectivity of the tests and measures, variability in selection of tests and potential discrepancies in interpretation of these tests could have impacted the impairment prevalence.

Additionally, inconsistencies in the assessment data were observed which could be contributed to the acute nature of the injury and patient's tolerance to testing. Hence, all tests and measures were not conducted on all the patients, thereby introducing bias in the reported prevalence of impairments. Also, the cross-sectional design of the study makes it difficult to

ascertain if the impairments were present prior to sustaining concussion or were the result of concussion. Hence, a cause and effect relationship could not be established.

Owing to the retrospective design, it was not possible to evaluate if the patients received any assistance from the parents or clinicians to complete the DHI-CA. This may have introduced bias in the patient response if they received any assistance. Also, inadequate sample size for the CFA and non-normal distribution of the data could have impacted the results.

Recommendations for future research

The limitations of this dissertation serve as a guiding point for further research. Study 1 identified various methodological inconsistencies in the included studies. Hence, future reliability studies with adequate power and strong methodological designs are recommended to evaluate reliability of postural control measures in typically developing children and adolescents. Since, validity and responsiveness are other measurement properties that are essential for clinical applicability of a measure, future systematic reviews should be conducted to describe validity and responsiveness of the postural control measures in in this population.

Study 2 highlighted several limitations in terms of tests and measures used in terms of sample bias, subjectivity of the tests and measures and limitation in their applicability. Future studies with larger samples from multiple geographical locations is recommended to explore the impairments further. It is recommended that future studies may focus on developing age appropriate screening tools to examine cervical spine impairments in children and adolescents post-concussion. Additionally, a comparative study must be done between individuals' post-concussion to the individuals who did not sustain a concussion to provide a direction towards contribution of concussion to the impairments related to the cervical spine that were observed in this study.

Study 3 revealed limitations in the current factor structure of the scale. Future research using IRT with Rasch analysis on a larger sample should be performed to revise the scale, and then to further explore its measurement properties.

Conclusion and clinical implication

The results of these studies provide us with the data on measurement properties of the postural control measures in typically developing youth, description of impairment frequencies related to cervical spine post-concussion and psychometric properties of the DHI-CA in post-concussion children and adolescents.

The findings of this review suggest that among the static postural control measures, BESS demonstrates acceptable reliability across studies and may be used for evaluation of static postural control in typically developing children. The CTSIB may provide reliable data when used with the AccuGait force platform. Among the dynamic postural control measures, TUG demonstrated good reliability and can be used cautiously to evaluate dynamic postural control. However, single study observations and methodological inconsistencies warrant cautious interpretation of findings. Studies with stronger methodological design in future are needed to draw meaningful conclusions.

This study has attempted to characterize specific cervical spine impairments in patients referred for physical therapy after concussion. The findings of this study provide preliminary data to support the framework of a cervical spine evaluation tool in children and adolescents following concussion. Future studies should aim to develop screening tools to evaluate possible cervical spine impairments in patients with concussion and to refer for a thorough cervical spine evaluation if cervical spine impairments are suspected.

Finally, although DHI-CA demonstrated evidence of convergent validity, it failed to demonstrate discriminant validity. The DHI-CA demonstrated several limitations in terms of variability in the underlying factor structure, item redundancy in the scale, poor model fit and poor

diagnostic accuracy Hence, caution is recommended while interpreting the results obtained from the DHI-CA in clinical practice. Future studies should further explore the factor structure with adequate sample size. Other psychometric properties such as test-retest reliability of the DHI-CA should also be evaluated.

Future research agenda

Future research agenda will constitute of conducting a systematic review to examine validity and responsiveness of postural control measures in typically developing children and adolescents. A comparative study will be proposed to distinguish between children and adolescents with and without concussion to gain further insight on the contribution of concussion towards cervical spine impairments.

Additionally, refinement of the structure of the DHI-CA and examination its psychometric properties of the newer version in post-concussion children and adolescents will be considered. This will comprise of performing Rasch analysis and re exploring the factor structure along with further examination of validity, responsiveness and test-retest reliability of the DHI-CA with adequate sample size.

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Institutional Review Board Approval

Subject: Initial Study Approval for [HUM00126048]

SUBMISSION INFORMATION:

Study Title: Characterizing and treating post-concussion individuals with cervical and vestibular physical therapy: A retrospective chart review

Full Study Title (if applicable): Characterizing and treating post-concussion individuals with cervical and vestibular physical therapy: A retrospective chart review

Study eResearch ID: [HUM00126048](#)

Date of this Notification from IRB: 6/7/2017

Review: Expedited

Initial IRB Approval Date: 6/7/2017

Current IRB Approval Period: 6/7/2017 - 6/6/2018

Expiration Date: Approval for this expires at 11:59 p.m. on 6/6/2018

UM Federalwide Assurance (FWA): FWA00004969 (For the current FWA expiration date, please visit the [UM HRPP Webpage](#))

OHRP IRB Registration Number(s): IRB00001996

Supporting Documents: Data collection sheet. 0.01. This sheet list the variables that will be collected for all patients in the study.

Approved Risk Level(s):

Name	Risk Level
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HUM00126048	No more than minimal risk
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NOTICE OF IRB APPROVAL AND CONDITIONS:

The IRBMED has reviewed and approved the study referenced above. The IRB determined that the proposed research conforms with applicable guidelines, State and federal regulations, and the University of Michigan's Federalwide Assurance (FWA) with the Department of Health and Human Services (HHS). You must conduct this study in accordance with the description and information provided in the approved application and associated documents.

APPROVAL PERIOD AND EXPIRATION:

The approval period for this study is listed above. Please note the expiration date. If the approval lapses, you may not conduct work on this study until appropriate approval has been re-established, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS

APPROVED STUDY DOCUMENTS:

You must use any date-stamped versions of recruitment materials and informed consent documents available in the eResearch workspace (referenced above). Date-stamped materials are available in the “Currently Approved Documents” section on the “Documents” tab.

RENEWAL/TERMINATION:

At least two months prior to the expiration date, you should submit a continuing review application either to renew or terminate the study. Failure to allow sufficient time for IRB review may result in a lapse of approval that may also affect any funding associated with the study.

AMENDMENTS:

All proposed changes to the study (e.g., personnel, procedures, or documents), must be approved

in advance by the IRB through the amendment process, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

AEs/ORIOs:

You must inform the IRB of all unanticipated events, adverse events (AEs), and other reportable information and occurrences (ORIOs). These include but are not limited to events and/or information that may have physical, psychological, social, legal, or economic impact on the research subjects or other.

Investigators and research staff are responsible for reporting information concerning the approved research to the IRB in a timely fashion, understanding and adhering to the reporting guidance (<https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/guidance/adverse-events-aes-other-reportable-information-and-occurrences-orios-and-other-required-reporting>), and not implementing any changes to the research without IRB approval of the change via an amendment submission. When changes are necessary to eliminate apparent immediate hazards to the subject, implement the change and report via an ORIO and/or amendment submission within 7 days after the action is taken. This includes all information with the potential to impact the risk or benefit assessments of the research.

SUBMITTING VIA eRESEARCH:

You can access the online forms for continuing review, amendments, and AEs/ORIOs in the eResearch workspace for this approved study (referenced above).

MORE INFORMATION:

You can find additional information about UM's Human Research Protection Program (HRPP)

in the Operations Manual and other documents available at: <http://research-compliance.umich.edu/human-subjects>.

Michael Geisser Alan Sugar

Co-chair, IRBMED Co-chair, IRBMED

Institutional Review Board Continuing Review Approval

Subject: Scheduled Continuing Review [CR00067763] Approved for [HUM00126048]

SUBMISSION INFORMATION:

Study Title: Characterizing and treating post-concussion individuals with cervical and vestibular physical therapy: A retrospective chart review

Full Study Title (if applicable): Characterizing and treating post-concussion individuals with cervical and vestibular physical therapy: A retrospective chart review

Study eResearch ID: [HUM00126048](#)

SCR eResearch ID: [CR00067763](#)

SCR Title: HUM00126048_Continuing Review - Wed Mar 14 13:17:48 EDT 2018

Date of this Notification from IRB: 3/20/2018

Review: Expedited

Date Approval for this SCR: 3/20/2018

Current IRB Approval Period: 3/20/2018 - 3/19/2019

Expiration Date: Approval for this expires at 11:59 p.m. on 3/19/2019

UM Federalwide Assurance: FWA00004969 (For the current FWA expiration date, please visit the [UM HRPP Webpage](#))

OHRP IRB Registration Number(s): IRB00001996

Approved Risk Level(s) as of this Continuing Report:

Name	Risk Level
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HUM00126048 No more than minimal risk

NOTICE OF IRB APPROVAL AND CONDITIONS:

The IRBMED has reviewed and approved the scheduled continuing review (SCR) submitted for the study referenced above. The IRB determined that the proposed research continues to conform with applicable guidelines, State and federal regulations, and the University of Michigan's Federalwide Assurance (FWA) with the Department of Health and Human Services (HHS). You must conduct this study in accordance with the description and information provided in the approved application and associated documents.

APPROVAL PERIOD AND EXPIRATION DATE:

The updated approval period for this study is listed above. Please note the expiration date. If the approval lapses, you may not conduct work on this study until appropriate approval has been re-established, except as necessary to eliminate apparent immediate hazards to research subjects or others. Should the latter occur, you must notify the IRB Office as soon as possible.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS

APPROVED STUDY DOCUMENTS:

You must use any date-stamped versions of recruitment materials and informed consent documents available in the eResearch workspace (referenced above). Date-stamped materials are available in the “Currently Approved Documents” section on the “Documents” tab.

In accordance with 45 CFR 46.111 and IRB practice, consent document(s) and process are considered as part of Continuing Review to ensure accuracy and completeness. The dates on the

consent documents, if applicable, have been updated to reflect the date of Continuing Review approval.

RENEWAL/TERMINATION:

At least two months prior to the expiration date, you should submit a continuing review application either to renew or terminate the study. Failure to allow sufficient time for IRB review may result in a lapse of approval that may also affect any funding associated with the study.

AMENDMENTS:

All proposed changes to the study (e.g., personnel, procedures, or documents), must be approved in advance by the IRB through the amendment process, except as necessary to eliminate apparent immediate hazards to research subjects or others. Should the latter occur, you must notify the IRB Office as soon as possible.

AEs/ORIOs:

You must continue to inform the IRB of all unanticipated events, adverse events (AEs), and other reportable information and occurrences (ORIOs). These include but are not limited to events and/or information that may have physical, psychological, social, legal, or economic impact on the research subjects or others.

Investigators and research staff are responsible for reporting information concerning the approved research to the IRB in a timely fashion, understanding and adhering to the reporting guidance (<https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/guidance/adverse-events-aes-other-reportable-information-and-occurrences-orios-and-other-required-reporting>), and not implementing any changes to the research without IRB approval of the change via an amendment submission. When changes are necessary to eliminate

apparent immediate hazards to the subject, implement the change and report via an ORIO and/or amendment submission within 7 days after the action is taken. This includes all information with the potential to impact the risk or benefit assessments of the research.

SUBMITTING VIA eRESEARCH:

You can access the online forms for continuing review, amendments, and AE/ORIO reporting in the eResearch workspace for this approved study, referenced above.

MORE INFORMATION:

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Michael Geisser Alan Sugar

Co-chair, IRBMED Co-chair, IRBMED

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